



INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA26908776161269V
Certificate Issued Date	:	28-Mar-2023 03:52 PM
Account Reference	:	NONACC (FI) / kaksfcl08/ BANGALORE8/ KA-RJ
Unique Doc. Reference	:	SUBIN-KAKAKSFCL0838691140716328V
Purchased by	:	PAREXEL INTERNATIONAL CLINICAL RESEARCH PVT LTD
Description of Document	:	Article 4 Affidavit
Description	:	AFFIDAVIT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	PAREXEL INTERNATIONAL CLINICAL RESEARCH PVT LTD
Second Party	:	NA
Stamp Duty Paid By	:	PAREXEL INTERNATIONAL CLINICAL RESEARCH PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)



Please write or type below this line

CLINICAL STUDY AGREEMENT

263708 C1071007 IND 1284 CSA Verma English 20230411 1.0

Statutory Alert:

1. The authenticity of this Stamp certificate should be verified at 'www.shcilestamp.com' or using e-Stamp Mobile App of Stock Holding. Any discrepancy in the details on this Certificate and as available on the website / Mobile App renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.



CLINICAL STUDY AGREEMENT

Among

Parexel International Clinical Research Private Limited

And

Dr Sanjiv Verma

And

Swami Rama Himalayan University

Pfizer Protocol # C1071007

This Clinical Study Agreement (“Agreement”) among

Parexel International Clinical Research Private Limited, with a place of business at CoWrks, Coworking Spaces Pvt.Ltd-RMZ Eco World, Ground floor, Bay Area- Adjacent to Building 6A, Outer Ring Road, Devarabeesanahalli Village, Bengaluru -560103, Karnataka, India (“CRO”) and

Dr Sanjiv Verma with a place of business at ‘Himalayan Institute of Medical Sciences’ a unit of Swami Rama Himalayan University, Jolly Grant- 248 016, Dehradun, Uttarakhand, India. (“Principal Investigator”),

and

Swami Rama Himalayan University, with a place of business at a University established under section 2(f) of the UGC Act, 1956 and enacted vide Uttarakhand Act no. 12 of 2013, having its registered office at Swami Ram Nagar, Jolly Grant- 248 016, Dehradun, Uttarakhand, India through its Registrar Dr. Susheela Sharma (“Institution”),

when signed by all parties, is effective as of 11 Apr 2023.

Pfizer Inc. (“Pfizer”) wishes to sponsor a clinical study trial/entitled “MAGNETIS MM-7 / A RANDOMIZED, 2-ARM, PHASE 3 STUDY OF ELRANATAMAB (PF-06863135) VERSUS LENALIDOMIDE IN PATIENTS WITH NEWLY DIAGNOSED MULTIPLE MYELOMA AFTER UNDERGOING AUTOLOGOUS STEM-CELL TRANSPLANTATION” (“Study”) to be conducted by Principal Investigator at Institution under the Pfizer protocol identified above (“Protocol”). Pfizer has delegated responsibility for management of this Study, including contracting and Study monitoring, to CRO, and has authorized CRO to bind Pfizer to all commitments within this Agreement identified as belonging to Pfizer.



The parties agree as follows:

1. Responsibilities

- 1.1 Investigators and Research Staff. The Study will be conducted by Principal Investigator, namely Dr. Sanjiv Verma ("Principal Investigator") at a facility that is identified as a 'clinical trial site' under the Rules. Principal Investigator an employee of Institution and is authorized by Institution to conduct the Study at Institution under a separate agreement between Principal Investigator and Institution. Principal Investigator will ensure that only individuals who are appropriately trained, experienced and qualified assist in the conduct of the Study as investigators, sub-investigators or research staff. The Principal Investigator shall sign an undertaking in the form prescribed in **Table 4** of the **Third Schedule** of the Rules. Principal Investigator shall further ensure that the Study is subject to continuing oversight by the IRB/IEC throughout its conduct.
- 1.2 Compliance Obligations. Principal Investigator and Institution are responsible to CRO and Pfizer for compliance by all Study personnel with the terms of this Agreement, the Protocol, the applicable provisions of the Drugs and Cosmetics Act, 1940 ("Act"), the Rules, and International Conference on Harmonization Good Clinical Practice ("ICH GCP") guidelines, ethical guidelines for Biomedical Research on Human Participants issued by the Indian Council of Medical Research, as well as applicable law, regulations, and governmental guidance, including without limitation, the laws of the Republic of India. The Institution and CRO shall be jointly responsible for obtaining requisite permissions and approvals for the conduct of the Study in terms of applicable laws, including permission from the Central Licensing Authority. The Institution also undertakes to abide by and comply with any statutory modifications/ amendments to the Rules, as may be effective from time to time. Institution is responsible for compliance by all personnel who are employees or contractors of Institution, and Principal Investigator is responsible for compliance by any personnel not employed or contracted by Institution.
- 1.3 Pfizer GCP Training. Prior to enrollment of any Study Subjects (as defined in Section 4, Subject Enrollment), Principal Investigator and any sub-investigators will either complete or provide a valid certificate of the Pfizer-provided Good Clinical Practice training course ("Pfizer GCP Training"). Any investigators who later join the Study, in compliance with applicable laws including the Rules, will complete the Pfizer GCP Training or provide a valid certificate before performing Study-related duties.
- 1.4 Compliance with Global Trade Controls. The parties agree that activities under this Agreement may be subject to applicable import, export, and economic sanctions laws and regulations ("Global Trade Control Laws"). Institution and CRO will comply with all applicable Global Trade Control Laws.



- a. The parties confirm that none of the activities under this Agreement will (i) take place in a Restricted Market; (ii) involve individuals ordinarily resident in a Restricted Market; and (iii) involve companies, organizations, or Governmental Entities from a Restricted Market. "Restricted Market" shall mean the Crimean Peninsula, Cuba, the Donbass Region, Iran, North Korea, Sudan, and Syria.
 - b. Each party represents and warrants that (i) it is not on any Restricted Party Lists (defined below); (ii) it is not owned or controlled by any individual or entity on any Restricted Party Lists; and (iii) that it will not involve any individual or entity on any Restricted Party Lists in the activities under this Agreement. In the event that an individual or entity on a Restricted Party List is included in activities under this Agreement, the party connected with such individual or entity will immediately notify the other party and suspend the relevant affected activities, including any and all affected payments, until the parties agree to go forward.
 - c. With respect to this Agreement, Restricted Party Lists include the Consolidated Screening List (https://www.export.gov/consolidated_screening_list); the Excluded Parties List System (<https://www.sam.gov>); and the Consolidated List of Persons, Groups, and Entities Subject to E.U. Financial Sanctions https://eeas.europa.eu/headquarters/headquarters-homepage/8442/consolidated-list-sanctions_en
- 1.5 The Institution shall ensure that the Principal Investigator shall conduct Study/clinical trials only with the permission of the Institutional Review Board (IRB)/ Independent Ethical Committee (IEC) after the examination of the risk and complexity involved in the trials proposed to be conducted and shall not in any instance conduct any higher number of Study/clinical trial not permitted by the IRB/IEC. The Institution shall indemnify the CRO and Pfizer, their respective employees and agents against any and all claims and proceedings (to include any settlements or reasonable legal and expert cost and expenses) arising out of or in connection with the Principal Investigator's failure to adhere to provisions of this Clause.
2. **Funding.** CRO will provide funding in support of this Study to Institution as delineated in Attachment A, Study Budget and Payment Terms, and subject to the terms specified in that Attachment. Institution certifies that payments to the Institution comply with applicable law and any applicable policies and procedure of the Institution.
- 2.1 **Payee.** As indicated in Attachment A, Institution is the payee for all Study funding. CRO's only payment obligation under this Agreement is to Institution. Allocation of funds between Institution and Principal Investigator is governed by a separate



agreement between those parties. Principal Investigator releases CRO and Pfizer from any obligation or liability related to the disbursement of funds by Institution.

- 2.2 **Investigator Meetings.** If Principal Investigator or other Study personnel are required to attend investigator meetings for this Study, CRO will arrange and pay directly for travel and accommodation and will cover the reasonable costs of meals in connection with those meetings, but does not provide compensation for such attendance.
- 2.3 **Disclosure by Pfizer.** In the interest of transparency relating to its relationships with investigators and Study sites or to ensure compliance with applicable local laws, Pfizer may publicly disclose the support it provides under this Agreement. Such a disclosure by Pfizer may identify both the Institution and the Principal Investigator, but will clearly differentiate between payments or other transfers of value to institutions and those made to individuals.
3. **Protocol.** Principal Investigator will conduct the Study and Study-related activities in accordance with the Protocol, including, but not limited to, the requirements relating to approval of the IRB / IEC (as laid out in Clause (B) of **Table 1 of Third Schedule** under the Rules) and the Licensing Authority under the Rules as also related to reporting / adverse event reporting in terms of the applicable laws.
 - 3.1 **Amendments.** The Protocol may be modified only by a written amendment, approved by Pfizer, the CRO, the responsible IRB/IEC and the Central Licensing Authority (“**Amendment**”) except, as described in the Protocol, for emergency changes necessary to eliminate immediate hazards and/or protect the safety of the Study Subjects (as defined in Section 4, Subject Enrollment). The Amendment(s) of the Protocol, if any, to eliminate immediate hazards and protect the safety of the Study Subject shall be immediately notified to the responsible IRB/IEC, provided that any administrative and/or logistic changes in the Protocol shall be notified to the Licensing Authority within 30 days in accordance with applicable laws.
 - 3.2 **No Additional Research.** No additional research may be conducted on Study Subjects (as defined in Section 4, Subject Enrollment) during the conduct of the Study or on biological samples collected during the conduct of the Study unless it is approved by Pfizer and documented as an Amendment to the Protocol in compliance with applicable laws.
4. **Subject Enrollment.** Principal Investigator has agreed to enroll qualified Study participants during the Pfizer-specified enrollment period, unless CRO, upon Pfizer’s prior instructions, modifies the enrollment period by written notice. A qualified participant is one who meets all Protocol criteria for inclusion in the Study (“**Study Subject**”).



5. Study Conduct

- 5.1 Charging Study Subjects. Neither Principal Investigator nor Institution will charge a Study Subject or third-party payer for Investigational Drug (see Section 8, Investigational Drug) or for any services reimbursed by CRO under this Agreement.
- 5.2 Safety Measures and Serious Protocol or ICH GCP Breaches. Principal Investigator will inform CRO immediately of any urgent safety measures taken by Principal Investigator to protect Study Subjects against immediate hazard. Principal Investigator and Institution will inform CRO immediately of any deviations or serious breaches of the Protocol, the Act, the Rules, the GCP Guidelines or of ICH GCP guidelines of which Principal Investigator or Institution becomes aware, adverse drug reactions / adverse events / serious adverse events reportable in accordance with the applicable laws, and new information that may adversely affect safety of the Study Subjects or the conduct of the Study.
- 5.3 The Institution shall ensure that adequate information in relation with the Study is provided to the Study Subject by the Principal Investigator in compliance with the Rules and applicable laws. The Principal Investigator shall document the standard operating procedures for the Study and shall also strictly comply with all the requirements prescribed under the Rules and the GCP Guidelines.

6. Data Protection and FDA Financial Disclosure

- 6.1 Personal Data. Personal data is any information from which it is possible to identify an individual. Personal data that concerns health information, including physical, physiological and mental health condition, biometric information and medical records and history, is sensitive personal data. Personal data collected in association with the Study will include personal data relating to the Principal Investigator, sub-investigators, research staff, third parties, and Study Subjects (which could include sensitive personal data) (collectively "**Personal Data**"). Such Personal Data may be subject to specific legislation relating to its processing, storage, transfer and use. Principal Investigator and Institution will comply with all relevant laws relating to the protection and use of Personal Data and data privacy in their conduct and reporting of the Study and shall ensure that the provider of Personal Data has given his consent and has the knowledge of the fact of collection, purpose of usage, intended recipients and storage of the information. Principal Investigator and Institution will take all appropriate technical and organizational measures to prevent damage to, or disclosure, unauthorized or unlawful processing, or accidental loss or destruction of such Personal Data. CRO and Pfizer will take appropriate measures to protect the confidentiality and security of all Personal Data that they receive in connection with the Study.
- 6.2 Use by CRO and Pfizer. Personal Data will be processed and used for the purposes of administration of this Agreement and in connection with the Study. Information



relating to the Principal Investigator, sub-investigators, and research staff will be held on one or more databases for the purpose of determining their involvement in future research and in order to comply with any regulatory requirements.

- 6.3 **Financial Disclosure.** Where the Study is deemed by Pfizer to be a “covered study” for the purpose of the United States Food and Drug Administration regulation entitled “*Financial Disclosure by Clinical Investigators*” (the “**FDA Regulation**”), Principal Investigator agrees, and Principal Investigator or Institution, as appropriate, will ensure that any sub-investigator engaged in the Study agrees, to disclose to CRO and Pfizer all relevant financial and other information (including details of equity interests in Pfizer or any of its affiliates) relating to the Principal Investigator or sub-investigators, as the case may be (and, where relevant, spouse and dependants of Principal Investigator or sub-investigator) as required by CRO to enable Pfizer to comply with the FDA Regulation.
- 6.4 **Disclosure and Transfer.** Some of the Personal Data discussed in this Section 6 may be disclosed or transferred to other members of the CRO or Pfizer group of companies, to representatives and contractors working on behalf of the CRO or Pfizer group, and to regulatory authorities across the world. The Institution will ensure that all necessary consents are in place to comply with the provisions of this Section 6 with respect to any affected employees and contractors of Institution. Principal Investigator will ensure such consent for any individuals working under Principal Investigator’s direction and control who are not employees or contractors of Institution.

7. Informed Consent and Subject Recruitment.

- 7.1 **Informed Consent.** The Institution/Principal Investigator shall be responsible to provide information, including the information on the right to claim compensation in case of trial related injury or death, to the Study Subject through the informed consent process as set out in the Rules. The Institution and Principal Investigator will ensure that informed consent is obtained from each Study Subject (and if applicable, from any legally authorized representative) in the Informed Consent Form prescribed under **Table 3** of the **Third Schedule** of the Rules, as approved by the IRD/IEC, along with an audio visual recording of the informed consent in accordance with the applicable laws. Any recording will be taken and preserved in accordance with applicable data privacy laws and regulations. This obligation of taking and preserving the written consent and the audio- visual recording will also apply to any re-consent process required during the course of the Study. Principal Investigator will provide CRO and/or Pfizer an opportunity to review and approve the content of the informed consent document (including any revisions made during the course of the Study) before it is used. Principal Investigator must not make any changes to this document without the prior written approval of the CRO or Pfizer (including any revisions made during the course of the Study or required by IRB/IEC), and such approval is to be obtained before the revised informed consent document is used in respect of the Study.



- 7.2 **Subject Recruitment.** Principal Investigator will ensure that all Study-specific subject recruitment methods, procedures and materials have prior IRB/IEC written approval and comply with all applicable law, regulations and governmental guidance.
8. **Investigational Drug.** CRO will arrange for Institution to receive, at no charge, sufficient quantities of the Pfizer product that is being studied (“**Pfizer Drug**”) to allow Principal Investigator to conduct the Study. The CRO is *inter alia* obligated to apply for and obtain a license for import from the Central Licensing Authority in prescribed form under the Rules. Unless otherwise indicated in Attachment A (Study Budget and Payment Terms), CRO will also arrange for Institution to receive at no charge, or will cover the costs of, any other Protocol-required drugs (e.g., placebo, comparator drug, concomitant drug). Any other Protocol-required drug that CRO or Pfizer provides or covers the cost of is, together with the Pfizer Drug, considered “**Investigational New Drug**”.
- 8.1 **Custody and Dispensing.** Principal Investigator will maintain appropriate control of supplies of Investigational New Drug and will not administer or dispense it to anyone who is not a Study Subject, or provide access to it to anyone except Study personnel.
- 8.2 **Use.** Principal Investigator will use Investigational New Drug only as specified in the Protocol. Any other use of Investigational New Drug by Principal Investigator or Institution or permitted by Principal Investigator or Institution constitutes a material breach of this Agreement.
- 8.3 **Ownership of Pfizer Drug.** Pfizer Drug is and remains the property of Pfizer. Except for, and limited to, the use specified in the Protocol, Pfizer grants neither Principal Investigator nor Institution any express or implied intellectual property rights in the Pfizer Drug or in any methods of making or using the Pfizer Drug. The CRO agrees and acknowledges that it does not have the right to manufacture for sale or for distribution of the Investigational New Drug.
9. **Equipment or Materials.** CRO or Pfizer may provide, or arrange for a vendor to provide, certain equipment (“**Equipment**”) or proprietary materials for use by Principal Investigator or Institution during the conduct of Study. Such proprietary materials may include computer software, methodologies, rating scales and other instruments that are owned or licensed for use by CRO or Pfizer (collectively, “**Materials**”). Equipment or Materials to be provided for the Study and any requirements relating to them are described in Attachment C, Equipment and Materials which is incorporated into this Agreement by reference.
10. **Confidential Information.** During the course of the Study, Principal Investigator and the Institution and / or the Principal Investigator may receive or generate information that is confidential to CRO, Pfizer, or a Pfizer affiliate.



10.1 Definition. Except as specified in Section 10.2, Exclusions, below, “**Confidential Information**” includes

- a. the Protocol,
- b. the Investigator Brochure,
- c. Study Data (as defined in Section 11, Study Data, Biological Samples, and Study Records below),
- d. Biological Sample Analysis Data (as defined in Section 11, Study Data, Biological Samples, and Study Records, below),
- e. Attachment A (Study Budget and Payment Terms) to this Agreement, and
- f. any other information related to the Study, the Pfizer Drug, or CRO, Pfizer, or Pfizer affiliate technology, research, or business plans that CRO, Pfizer, or a Pfizer affiliate provides to Institution/Principal Investigator or Institution in writing or other tangible form and marks as CONFIDENTIAL or initially discloses orally and then summarizes and confirms in writing as CONFIDENTIAL within 30 days after the date of oral disclosure. Information of the type described in this Section 10.1.f. that is disclosed orally will also be considered Confidential Information even if not later confirmed in writing if the confidential nature of the disclosure is reasonably apparent to the other party.

10.2 Exclusions. Confidential Information does not include information that

- a. is in the public domain at the time of disclosure or during the term of this confidentiality obligation by means other than breach of this Agreement by Principal Investigator or Institution,
- b. is already known to Principal Investigator or Institution at the time of disclosure and is free of any obligations of confidentiality,
- c. is obtained by Principal Investigator or Institution, free of any obligations of confidentiality, from a third party who has a lawful right to disclose it, or
- d. is independently developed, as documented by written records, by individuals within Institution who had no access to Confidential Information.

10.3 Obligations of Confidentiality. Unless CRO or Pfizer provides prior written consent, Principal Investigator and Institution may not use Confidential Information for any purpose other than that authorized in this Agreement, nor may they disclose Confidential Information to any third party except as authorized in this Agreement or as required by law, including applicable regulations.

- a. CRO and Pfizer specifically authorize any required disclosure of Confidential Information to IRB/IEC or regulatory authority representatives.
- b. Permitted uses of Study Data and Biological Sample Analysis Data are described in Section 15 (Publications) of this Agreement and use of



Personal Data is discussed in Section 6 (Data Protection and FDA Financial Disclosure) and 12.2 (Pfizer Representative Personal Data).

10.4 **Disclosure Required by Law.** If disclosure of Confidential Information beyond that expressly authorized in this Agreement is required by law, that disclosure does not constitute a breach of this Agreement so long as the party disclosing the information

- a. notifies CRO in writing as far as possible in advance of the disclosure so as to allow CRO or Pfizer to take legal action to protect its Confidential Information,
- b. discloses only that Confidential Information required to comply with the legal requirement, and
- c. continues to maintain the confidentiality of this Confidential Information with respect to all other third parties.

10.5 **Survival of Obligations.** For Confidential Information other than Study Data and Biological Sample Analysis Data (as defined in Section 11, Study Data, Biological Samples, and Study Records), these obligations of nonuse and nondisclosure survive termination of this Agreement and continue for a period of five years after termination. Confidentiality obligations for Study Data and Biological Sample Analysis Data survive for as long as the party retains this information, subject to the permitted uses described in Section 15 (Publications) of this Agreement.

10.6 **Return of Confidential Information.** If requested by CRO and/or Pfizer in writing, Principal Investigator and / or Institution will return all Confidential Information except that required to be retained at the Study site or by Principal Investigator by applicable regulation. However, Principal Investigator and Institution may each retain a single archival copy of the Confidential Information to determine the scope of obligations incurred under this Agreement.

11. **Study Data, Biological Samples, and Study Records**

11.1 **Study Data.** During the course of the Study, Principal Investigator will collect certain data, as specified in the Protocol, and submit it to CRO, Pfizer or Pfizer's agent ("Study Data"). Principal Investigator will ensure accurate and timely collection, recording, and submission of Study Data, including adhering to timelines for data entry set out in the *CRF Completion Requirements* document provided to Principal Investigator by CRO or Pfizer.

- a. **Ownership of Study Data.** Subject to Principal Investigator's right to use Study Data to publish the results of the Study (see Section 15, Publications), Pfizer is the exclusive owner of all Study Data. Retained Samples and any non-Protocol data generated by Institution from its use of Retained Samples under Section 3.2 of this Agreement remain the property of Institution.



- b. Medical Records. Study Subject-related medical records that are not submitted to CRO or Pfizer may include some of the same information as is included in Study Data; however, neither CRO nor Pfizer makes any claim of ownership to those documents or the information they contain.
- c. Data Review by CRO. CRO and/or Pfizer will review the Study Data it receives on an ongoing basis. CRO and/or Pfizer will comply with applicable regulations requiring notification of participating investigators of new safety information about the Pfizer Drug (as defined in Section 8 of this Agreement). CRO and/or Pfizer further commits to promptly notify Institution/ Principal Investigator of any other new information of which CRO and/or Pfizer becomes aware that could affect the safety of the Study Subjects or influence the conduct of the Study.
- d. Study Results. After analysis of Study Data from all sites is complete, CRO or Pfizer will provide Institution/Principal Investigator with a summary of the overall results of the Study. CRO and Pfizer encourage Institution/Principal Investigator to communicate the results, as appropriate, to the Study Subjects. If within two years after Study completion Pfizer identifies results that could affect Study Subject safety, CRO or Pfizer, in consultation with the IRB/IEC as appropriate, will cooperate with Principal Investigator or Institution to ensure that those results are appropriately communicated to the Study Subjects by Principal Investigator or Institution.

11.2 Biological Samples. If so specified in the Protocol and the informed consent document, Principal Investigator may collect and provide to CRO, Pfizer or their designee biological samples obtained from Study Subjects (e.g., blood, urine, tissue, saliva, etc) for testing that is not directly related to Study Subject care or safety monitoring, such as pharmacokinetic, pharmacogenomic, or biomarker testing (“**Biological Samples**”).

- a. Use. Neither Principal Investigator nor Institution will use Biological Samples collected under the Protocol in any manner or for any purpose other than that described in the Protocol. CRO and Pfizer will use Biological Samples only in ways permitted by the informed consent under which they were obtained.
- b. Analysis Data. CRO, Pfizer, or their designees will test Biological Samples as described in the Protocol. Unless otherwise specified in the Protocol, neither CRO nor Pfizer plan to provide the results of these tests (“**Biological Sample Analysis Data**”) to Principal Investigator or Study Subject. If CRO or Pfizer does provide Biological Sample Analysis Data to Principal Investigator, that data will be subject to the provisions of Section 11.1 (Study Data) of this Agreement.



c. Ownership. Pfizer is the exclusive owner of all Biological Samples and Biological Sample Analysis Data.

11.3 Study Records. On behalf of Principal Investigator and itself, Institution will retain each Study Subject's Study records, which include the Principal Investigator's copies of all Study Data as well as relevant source documents (collectively, "**Study Records**"), under storage conditions conducive to their stability and protection, for a period of 15 years after termination of the Study. Institution agrees to contact Pfizer at InvestigatorRecords@Pfizer.com prior to destroying any Study Records and Principal Investigator and Institution further agree to permit Pfizer to ensure that the Study Records are retained for a longer period if necessary, at Pfizer's expense, under an arrangement that protects the confidentiality of the records (e.g., secure off-site storage).

12. Monitoring, Inspections, and Audits

12.1 Monitoring. CRO intends to monitor Study conduct. Pfizer, or an external service provider acting on its behalf, has the right, but not the obligation, to co-monitor the Study. Upon reasonable notice and during regular business hours, Principal Investigator and Institution will permit CRO or Pfizer representatives access to the premises, facilities, Study Records, sub-investigators, and research staff as required to monitor Study conduct. CRO or Pfizer will promptly notify Principal Investigator of any monitoring findings that could affect the safety of Study Subjects or influence the conduct of the Study. Principal Investigator will inform Study Subjects of such findings as appropriate.

12.2 Pfizer Representative Personal Data. If in the support of a clinical trial, Pfizer representatives are required to submit to Institution and Principal Investigator any Personal Data, including but not limited to, name, address, phone number, government identifier, or birthdate ("**Pfizer Representative Personal Data**"), Institution and Principal Investigator will:

- a. protect the confidentiality of Pfizer Representative Personal Data using the same or similar standards Institution uses for its own employees;
- b. not sell or disclose Pfizer Representative Personal Data to any third party except as required by law;
- c. impose similar confidentiality and security obligations, by contract, on any contracted service providers with whom Institution may share Pfizer Representative Personal Data;
- d. take appropriate measures to protect against any unauthorized use or disclosure of Pfizer Representative Personal Data and will promptly notify Pfizer of any breach of this provision.



12.3 **Inspections and Audits.** Principal Investigator and Institution acknowledge that the Study is subject to inspection by regulatory authorities worldwide, including the United States FDA, and that such inspections may occur prior to commencement, during or after completion of the Study and may include auditing of Study Records. CRO or Pfizer may also audit Study Records during or after the Study as part of its monitoring of Study conduct.

- a. **Notification.** Principal Investigator will notify CRO as soon as reasonably possible if the Study or site is inspected or scheduled to be inspected by a regulatory authority in relation to the Study.
- b. **Right to be Present.** If not prohibited by law, Pfizer or CRO will have the right to be present during, and participate in, any such inspection, audit, investigation, or regulatory action.
- c. **Cooperation.** Principal Investigator and Institution will cooperate with regulatory authority and CRO or Pfizer representatives in the conduct of inspections and audits and will ensure that Study Records are maintained in a way that facilitates such activities.
- d. **Resolution of Discrepancies.** Principal Investigator will promptly resolve any discrepancies that are identified between the Study Data and the Study Subject's medical records.
- e. **Inspection Findings and Responses.** Principal Investigator and Institution will promptly forward to CRO and Pfizer copies of any inspection findings that either receives from a regulatory authority in relation to the Study. Whenever feasible and permitted by law, Principal Investigator and Institution will also provide CRO and Pfizer with an opportunity to prospectively review and comment on any responses to regulatory authority inspections in regard to the Study.

12.4 **Study Conduct Evaluations.** CRO, Pfizer or Pfizer's external service providers may document and evaluate the performance of Institution and Principal Investigator in the conduct of the Study. CRO and Pfizer will use these evaluations solely for internal purposes.



13. **Remedies for Breach of Certain Study Obligations.** In the event Principal Investigator or Institution fails to comply with any of its obligations set out in Sections 3 (Protocol), 7 (Informed Consent and Subject Recruitment), 11 (Study Data, Biological Samples, and Study Records) and 12 (Monitoring, Inspections, and Audits) of this Agreement, or the requirements of the Protocol relating to adverse event reporting, ethical conduct of the Study, and IRB/IEC review, in addition to its right to terminate the Study immediately under Section 18.1.c(2), CRO will have recourse to either or both of the following alternative remedies:

- a. Suspension of Study Subject enrollment, if the Study is not yet fully enrolled, and
- b. Suspension of all payments by CRO

Any suspension of enrollment or payment will continue until Principal Investigator and Institution return to compliance with their Study obligations, as determined by CRO. Use of either or both of the above remedies does not preclude CRO or Pfizer from exercising its right to immediately terminate the Study if Principal Investigator and Institution do not become compliant.

14. **Inventions**

- 14.1 **Notification.** If the conduct of Study results in any invention or discovery whether patentable or not (“**Invention**”), Principal Investigator will promptly inform CRO and Pfizer.
- 14.2 **Assignment.** Principal Investigator or Institution, as applicable, will assign, or ensure that inventors assign, all interest in any such Invention to Pfizer, free of any obligation or consideration beyond that provided for in this Agreement.
- 14.3 **Assistance.** Principal Investigator and Institution will provide reasonable assistance to Pfizer in filing and prosecuting any patent applications relating to Invention, at Pfizer’s expense.

15. **Publications.** Pfizer supports the exercise of academic freedom and has no objection to publication by Principal Investigator of the results of the Study based on information collected or generated by Principal Investigator, whether or not the results are favorable to the Pfizer Drug, subject to the Principal Investigator maintaining the privacy and confidentiality of the Study Subjects in compliance with applicable laws.

- 15.1 **Prepublication Review.** Principal Investigator will provide Pfizer an opportunity to review any proposed publication or any other type of disclosure of the results of the Study (collectively, “**Publication**”) before it is submitted or otherwise disclosed. Pfizer will review for unprotected Inventions (see Section 14, Inventions) and may also provide comments on content. Principal Investigator will consider any such comments in good faith but is under no obligation to incorporate any Pfizer



suggestions.

- a. Submission to Pfizer. Principal Investigator will provide any Publication to Pfizer at least 30 days before it is submitted for publication or otherwise disclosed. If any patent action is required to protect intellectual property rights, Principal Investigator agrees to delay the disclosure for a period not to exceed an additional 60 days.
- b. Redaction of Confidential Information. Principal Investigator will, on request, remove any previously undisclosed Confidential Information before disclosure, except for any Study- or Pfizer Drug-related information necessary to the appropriate scientific presentation or understanding of the Study results.

15.2 Multi-Center Studies. If Study is part of a multi-center trial, Principal Investigator and Institution agree that the first Publication is to be a joint Publication covering all Study sites, and that any subsequent Publications by Principal Investigator will reference that primary Publication. However, if a joint manuscript has not been submitted for publication within 12 months of completion or termination of Study at all participating sites, Principal Investigator is free to publish separately, subject to the other requirements of this Section 15.

15.3 Standards. For all Publications relating to the Study, Principal Investigator will comply with the authorship guidelines in the *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals* (<http://www.icmje.org/icmje-recommendations.pdf>) provided by the International Committee of Medical Journal Editors.

15.4 Disclosure of Support. Principal Investigator will disclose Pfizer sponsorship and financial support of the Study in any publication of Study results. The Institution will at all times ensure that such Publications are made in strict compliance with laws prevalent in India

15.5 Study Registration by Pfizer. Pfizer commits to register, on the National Institutes of Health Clinical Trials Data Bank (www.clinicaltrials.gov), all Pfizer-sponsored Phase 1 through 4 interventional and non-interventional studies that involve the use of a Pfizer product and evaluate the safety or efficacy of that product. Pfizer will also register Pfizer-sponsored studies on other listings of ongoing studies maintained by competent regulatory authorities where there is a regulatory requirement to do so. Pfizer also commits to register on Indian Council for Medical Research's Clinical Trial Registry before the enrollment of the first Study Subject.

16. Indemnification and Research Injury. CRO does not provide any indemnification under this Agreement. The Pfizer Indemnification and Research Injury Policy applicable to this Study is appended to this Agreement as Attachment B.



17. Assignment and Delegation

- 17.1 By Principal Investigator or Institution. Neither Principal Investigator nor Institution shall assign his/her/its rights or delegate or subcontract any duties under this Agreement without written permission from CRO and Pfizer. If CRO and Pfizer authorize delegation or subcontracting, the party that delegated or subcontracted its duties remains responsible to CRO for the performance of those duties.
- 17.2 By CRO. CRO may freely assign any or all of its rights and delegate any or all of its duties under this Agreement to Pfizer (subject to the prior written consent of Pfizer). If CRO assigns all rights and delegates all duties to Pfizer, CRO or Pfizer will notify Principal Investigator and Institution in writing. Any other assignment of rights and obligations of the CRO under this Agreement shall be mutually agreed between the CRO and Pfizer and notified to the Institution.

18. Termination

- 18.1 Termination Events. Termination of this Agreement will be triggered by the earlier of any of the following events.
 - a. Disapproval by IRB/IEC. If the Study cannot be initiated because of IRB/IEC disapproval, this Agreement will terminate.
 - b. Study Completion. This Agreement will terminate when the Study is complete, which means the conclusion of all Protocol-required activities for all enrolled Study Subjects.
 - c. Early Termination of Study. This Agreement will terminate if the Study is terminated early as described below.
 - (1) Termination of Study Upon Notice. CRO or Pfizer may terminate the Study for any reason upon 30 days' written notice to Principal Investigator and Institution.
 - (2) Immediate Termination of Study by CRO or Pfizer. CRO or Pfizer may terminate the Study immediately upon written notice to Principal Investigator and Institution for causes that include failure to enroll Study Subjects at a rate sufficient to achieve Study performance goals; material unauthorized deviations from the Protocol or reporting requirements; circumstances that in CRO's or Pfizer's opinion pose risks to the health or well-being of Study Subjects; regulatory authority actions relating to the Study or the Investigational New Drug; or any non-compliance by the Principal



Investigator or Institution with applicable laws, ICH GCP, or the terms of Section 20 (Anti-Corruption) of this Agreement.

- (3) Immediate Termination of Study by Principal Investigator or Institution. Principal Investigator or Institution may terminate the Study immediately upon notification to CRO if requested to do so by the responsible IRB/IEC or if such termination is required to protect the health of Study Subjects.
- (4) CRO or Pfizer shall have the right but not the obligation to terminate the Agreement, without further obligation to the Institution and/or Principal Investigator in the event that the Principal Investigator fails to declare to the IRB/IEC the number of clinical trials being conducted by the Principal Investigator and/or conducts clinical trial above such number as may have been decided by the IRB/IEC.

18.2 Effective Date of Agreement Termination. If termination of the Agreement is triggered by any of the events described in Section 18.1, above, the termination will be effective after receipt by CRO or Pfizer of all Protocol-required Study Data and Biological Samples generated up until termination; receipt of all payments due to any party; and completion by all parties of any remaining applicable Agreement obligations.

18.3 Payment upon Early Termination of Study. Except as otherwise indicated in this subsection, if the Study is terminated early, CRO will pay for work already performed, in accordance with Attachment A, less payments already made for such work. CRO will also cover any non-cancelable expenses, other than future personnel costs, so long as they were properly incurred and prospectively approved by CRO and only to the extent they cannot reasonably be mitigated. If the Study cannot be initiated because of disapproval by the IRB/IEC and through no fault of Principal Investigator or Institution, CRO will reimburse Principal Investigator or Institution, as applicable, for IRB/IEC fees and any other expenses that were prospectively approved, in writing, by CRO.

- a. Non-Compliance with Anti-Corruption Provision. If CRO or Pfizer terminates the Study because of Principal Investigator's or Institution's non-compliance with the terms of Section 20, Anti-Corruption, CRO and Pfizer will not provide any further payment under this Agreement, regardless of any activities that Principal Investigator or Institution has undertaken or third-party agreements that Principal Investigator or Institution has entered into before termination.

18.4 Institution's duty on Early Termination. The Institution should promptly inform the Study Subjects, the IRB/IEC as well as the Central Licensing Authority of such termination. The Institution should also ensure appropriate therapy and follow-up for the Study Subjects at no cost to Pfizer or CRO.



- 18.5 Return of Materials. Unless CRO instructs otherwise in writing, upon termination of the Agreement, Principal Investigator and Institution will promptly return all materials supplied by CRO or Pfizer for Study conduct, including unused Investigational New Drug, unused Case Report Forms, and any CRO or Pfizer-supplied Equipment and Materials.
- 18.6 Survival of Obligations. Obligations relating to Funding, Confidential Information, Study Records, Inventions, Publications, Indemnification and Research Injury, Suitability, and Anti-Corruption survive termination of this Agreement, as does any other provision in this Agreement, including Attachments, that by its nature and intent remains valid after the term of the Agreement.

19. Other Terms

- 19.1 Suitability. Principal Investigator and Institution each certify that he/she/it is licensed, registered, or otherwise qualified and suitable under applicable law, regulations, policies, or administrative requirements to conduct the Study and required Study-related activities or act as Study site, as applicable. Principal Investigator and Institution also each certify that he/she/it is not debarred under subsections 306(a) or (b) of the United States Federal Food, Drug, and Cosmetic Act and any applicable law, that there are no applicable regulations or other obligations, that there are no applicable regulations or other obligations that prohibit either party from conducting the Study and entering into this Agreement and that they will not use in any capacity the services of any person debarred under such law with respect to services to be performed under this Agreement. During the term of this Agreement and for three years after its termination, Institution and Principal Investigator will notify CRO promptly if any of these certifications need to be amended in light of new information.
- 19.2 Investigations, Inquiries, Warnings, or Enforcement Actions Related to Conduct of Clinical Research. Principal Investigator and Institution each certify that he/she/it is not the subject of any past or pending governmental or regulatory investigation, inquiry, warning, or enforcement action (collectively, “Agency Action”) related to its conduct of clinical research or the practice of medicine that has not been disclosed to CRO or Pfizer. Principal Investigator or Institution will notify CRO promptly if he/she/it receives notice of or becomes the subject of any Agency Action regarding compliance with ethical, scientific, or regulatory standards for the conduct of clinical research or the practice of medicine if the Agency Action relates to events or activities that occurred prior to or during the period in which the Study was conducted.
- 19.3 Use of Name. CRO and Pfizer reserve the right to identify the Principal Investigator and Institution in association with a listing of the Protocol in the United States National Institutes of Health (NIH) Clinical Trials Data Bank, the Indian Council



for Medical Research's Clinical Trial Registry and other publicly available listings of ongoing clinical trials, or other Study Subject recruitment services or mechanisms. Neither CRO nor Pfizer will otherwise use the name of Principal Investigator, Institution, or any of Institution's employees or contractors, and neither Principal Investigator nor Institution will use the name of CRO, Pfizer, or any of their respective employees or contractors, for promotional or advertising purposes without written permission from the party whose name will be used.

- 19.4 Relationship of the Parties. The relationship of Principal Investigator and Institution to CRO and Pfizer is one of an independent contractors and not one of partnership, agents and principal, employees and employer, joint venture, or otherwise.
- 19.5 Modification. Any modification to this Agreement shall be in writing, signed by the parties, and identified as an Amendment, except for certain mutually agreeable changes in the Study budget as identified in Attachment A.
- 19.6 No Waiver. Failure to assert a right under this Agreement does not constitute a waiver of that right in the future. No waiver of any right is effective unless in writing and signed by the party who waives the right.
- 19.7 Conflict with Attachments. If there is any conflict between this Agreement and any Attachments to it, the terms of this Agreement control. If there is any conflict between this Agreement and the Protocol, the Protocol will control as to any issue regarding treatment of Study Subjects, and the Agreement will control as to all other issues.
- 19.8 Affiliates. As used in this Agreement, the term "**affiliate**" means any entity that directly or indirectly controls, is controlled by, or is under common control with the named party.
- 19.9 Successors and Assigns. This Agreement will bind and inure to the benefit of the successors and permitted assigns of each party.
- 19.10 Third Party Beneficiary. Pfizer is an intended third-party beneficiary to this Agreement and is entitled to enforce directly any and all of its rights under it. If a third party acquires rights in the Pfizer Drug and Pfizer transfers sponsorship of the Study to the third party Pfizer may freely transfer any or all of its rights and obligations under this Agreement to the new sponsor.
- 19.11 Disclaimer of Warranties by CRO. THE PARTIES ACKNOWLEDGE THAT PFIZER HAS ENGAGED CRO TO PROVIDE SERVICES IN REGARD TO THIS PFIZER-SPONSORED CLINICAL STUDY. CRO HAS NOT PERFORMED ANY INDEPENDENT RESEARCH OR ANALYSIS



REGARDING THE SAFETY OR EFFICACY OF ANY INVESTIGATIONAL NEW DRUG OR OTHER MATERIALS OR TREATMENT PROCEDURES TO BE USED IN THIS STUDY AND THEREFORE CRO MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, CONCERNING THOSE DRUGS, MATERIALS, OR TREATMENT PROCEDURES, THE RESULTS TO BE OBTAINED BY ADMINISTERING THEM PURSUANT TO THE PROTOCOL, OR TO THEIR FITNESS FOR ANY PARTICULAR PURPOSE, OR TO ANY OTHER PFIZER OBLIGATION UNDER THE PROTOCOL OR THIS AGREEMENT.

- 19.12 Entire Agreement. This Agreement, including Attachments, represents the entire understanding between the parties relating to this subject matter. This Agreement supersedes all previous agreements between the parties (oral and written) relating to this Study, except for any obligations that, by their terms, survive independent of this Agreement.
- 19.13 Notices. Any notice required to be given hereunder shall be in writing and deemed to have been sufficiently given, (i) when delivered in person, (ii) on the next business day after mailing by overnight courier service, or, where overnight courier service is unavailable, by other expedited delivery provided by a recognized express courier, or (iii) when delivered via e-mail, provided the original is delivered via one of the preceding methods on or prior to the fifth (5th) business day after transmission of the e-mail, to the addresses specified below. Each notice shall specify the name and date of and parties to this Agreement.

CRO: notices@parexel.com

Parexel International Clinical Research Private Limited,
CoWrks, Coworking Spaces Pvt.Ltd-RMZ Eco World, Ground floor, Bay Area-
Adjacent to Building 6A, Outer Ring Road, Devarabeesanahalli Village
Bengaluru -560103, Karnataka, India.

Principal Investigator:

Dr Sanjiv Verma
HOD Medical Oncology and Hematology,
Himalayan Institute of Medical Sciences,
Swami Rama Himalayan University,
Swami Ram Nagar, Jolly Grant- 248016,
Dehradun, Uttarakhand, India.
Telephone: +91-9837121136
Email: skverma177@gmail.com



Institution:

Himalayan Institute of Medical Sciences,
Swami Rama Himalayan University,
Swami Ram Nagar, Jolly Grant- 248016,
Dehradun, Uttarakhand, India
Attention: Dr. Susheela Sharma, Registrar
Telephone: +91-7534010112
Email: reg@srhu.edu.in

Pfizer:

For submission of Publication only:
Dr. Anne Yver
Telephone: +33 (7) 89002895
E-mail: anne.yver@pfizer.com

- 19.15 **Counterparts and Signature.** This Agreement may be executed in two or more counterparts, each of which will be deemed to be an original, and all of which will together constitute one and the same agreement. The Agreement will be deemed to be fully executed when signed by each of the parties through written signature, Portable Document Format (PDF), validated digital signature, or other reliable electronic means, and delivered to the parties.
- 19.16 **Force Majeure.** Neither party will be liable for nonperformance or delays in performance that result from causes that are beyond its reasonable control and not attributable to its own acts or omissions. However, such nonperformance or delay is excused under this provision only for the duration of the qualifying event.
- 19.17 **Venue and Governing Law:** This Agreement is governed by the laws of India, without giving effect to any conflicts of laws principles; If the defendant in any litigation arising from this Agreement is Institution, the forum for such litigation will be the courts of Dehradun, Uttarakhand and the laws of India will apply. If the defendant in any litigation arising from this Agreement is CRO or Pfizer or both, the forum for such litigation will be the courts of the State of New York and New York law will apply
- 19.18 **Sponsor Insurance.** Pfizer will maintain insurance coverage of the kind and with liability limits appropriate to the circumstances to protect against any claims or liabilities that may arise from CRO or Pfizer obligations under this Agreement. On written request by Institution CRO will provide documentation of such Pfizer insurance coverage.



20. Anti-Corruption

20.1 Definitions

- a. **Government.** As used in this Agreement, “**Government**” includes all levels and subdivisions of governments (ie, local, regional, and national; administrative, legislative, and executive).
- b. **Government Official.** As used in this Agreement, “**Government Official**” includes (1) any elected or appointed non-US Government official (eg, a legislator or a member of a non-US Government ministry), (2) any employee or individual acting for or on behalf of a non-US Government official, non-US Government agency, or enterprise performing a function of, or owned or controlled by, a non-US Government (eg, a healthcare professional employed by a non-US Government hospital or researcher employed by a non-US Government university), (3) any non-US political party officer, candidate for non-US public office, or employee or individual acting for or on behalf of a non-US political party or candidate for public office, (4) any employee or individual acting for or on behalf of a public international organization, and (5) any member of a royal family or member of a non-US military.

20.2 Anti-Bribery and Anti-Corruption Principles. Principal Investigator and Institution have each received a copy of Pfizer’s International Anti-Bribery and Anti-Corruption Principles as an Attachment to this Agreement. Principal Investigator and Institution will ensure that they and any of their agents or subcontractors conducting Pfizer work will comply with the Anti-Bribery and Anti-Corruption Principles.

20.3 Warranties. Principal Investigator and Institution warrant to CRO and Pfizer the following:

- a. Any information that Principal Investigator or Institution provided to CRO or Pfizer as part of CRO’s or Pfizer’s anti-corruption due-diligence process is complete and accurate.
- b. If any response that Principal Investigator or Institution provided on the CRO or Pfizer due-diligence questionnaire in regard to Principal Investigator or Institution, any individuals identified in the questionnaire, or the Family Relatives (as defined in the questionnaire) of those individuals changes during the term of this Agreement, Principal Investigator or Institution will notify CRO.
- c. The funding provided by CRO or Pfizer under this Agreement will not cause Principal Investigator or Institution to do anything that would result in CRO



or Pfizer improperly obtaining or retaining business or gaining any improper business advantage.

- d. Principal Investigator and Institution have not and will not accept any payment or anything of value that would result in CRO or Pfizer improperly obtaining or retaining business or gaining any improper business advantage.
- e. Principal Investigator and Institution have not and will not in the future directly or indirectly offer or pay, or authorize the offer or payment of, any money or anything of value in an effort to influence any Government Official or any other person.

20.4 Funding Requirements. CRO will make no payment in addition to the funding set out in Attachment A (Study Budget and Payment Terms) in connection with this Agreement unless CRO has prospectively approved that expenditure in writing. All invoices and any supplemental documents that Principal Investigator and Institution submit to CRO or Pfizer under this Agreement must be truthful and show in reasonable detail what the requested payment is for. Principal Investigator and Institution will maintain true, accurate, and complete records (eg, invoices, reports, statements, and books) relating to the funding and expenditures for this Study.

20.5 Right to Audit. Pfizer has the right to take all reasonable steps and actions to ensure that each payment made by CRO on behalf of Pfizer is properly and legitimately used. To this end, Principal Investigator and Institution will permit, during the term of the Agreement and for three years after the final payment has been made under the Agreement, Pfizer's internal and external auditors access to any relevant books, documents, papers, and records of the Principal Investigator and Institution involving transactions related to the Agreement. Because this Agreement relates to a clinical study, there will be acceptable safeguards employed in such an audit to ensure confidentiality and protect the privacy of the Study Subjects.

20.6 Failure to Comply. If CRO or Pfizer terminates the Study or this Agreement because of Principal Investigator's or Institution's breach of any of the provisions in this Anti-Corruption section, Principal Investigator and Institution will be liable to Pfizer for damages or remedies as provided by law. Further, Principal Investigator and Institution will indemnify CRO and Pfizer against any third-party claim, fine, or penalty against CRO or Pfizer that results from such a breach by Principal Investigator or Institution.

[signature follows]



Agreed to and Accepted by:

Parexel International Clinical Research Private Limited

DocuSigned by:

CA8FD795E36E490...

Sanjay Vyas
Printed Name

EVP, India Country Head & MD
Title

Date: 4/20/2023

Dr. Sanjiv Verm

Date: 25/04/2023

Swami Rama Himalayan University

Dr. Susheela Sharma
Printed Name

Registrar
Title

Date: 24/4/2023

Attachments

Attachment A

Attachment C

Attachment C

Study Budget and Payment Terms

Indemnification and Research Injury Policy

Equipment and Materials

Pfizer International Anti-Bribery and Anti-Corruption Principles

Attachment A
Study Budget and Payment Terms
Pfizer Protocol # C1071007

1. **Payee Name and Address:** Payment of the sums due under this Agreement will be made payable to:

PI Name:	Dr Sanjiv Verma
Pfizer assigned Site ID:	1284
Payee:	SRHU SCIENTIFIC AND INDUSTRIAL RESEARCH

Payee	Payee Details
Protocol Number	C1071007
Site Number	1284
Payee Name	SRHU SCIENTIFIC AND INDUSTRIAL RESEARCH
Payee Address	HIHT.,
Address Line 2	Jollygrant
Address Line 3	P.O. Doiwala
Province/State/County	Uttarakhand
City	Dehradun
Postal Code	248016
Country	India
Payee Contact	Mr. Arvind Pal
Payee Contact Phone Number	8802459589
Remittance E-mail Address	<u>Aarvindpal181@gmail.com</u>
General Finance contract e-mail address if different from above	N/A
NPI	N/A
Tax ID (VAT/GST Registration/TIN/SSN)	05AAJH0463LIZC
Bank Account Holder Name	SRHU SCINTIFICSCIENTIFIC AND INDUSTRIAL RESEARCH
Bank Account Number	37200223663
IBAN (International Bank Account Number)	N/A
Bank Name	State Bank of India
Bank Number	0135 2412947
Bank Branch Number	10580
Bank Identification Code	SBIN0010580
Bank Type	Government Bank



The Institution must provide CRO, in writing, full payment instructions for the payee listed above, including completion of applicable payment processing forms, before any payments can be made under the Agreement. The Institution is obligated to inform CRO, in writing, of any changes or required updates of payment instructions and/or bank details.

No *other* payments will be made to the Institution until the following are completed: (1) execution of the Agreement, (2) submission of all regulatory documents to CRO, and (3) IRB approval.

If the Agreement is terminated before all payments are earned, the remainder must be returned to CRO immediately in accordance with **Section 13 (Refunds)** below. If Institution fails to do so, Pfizer, in its sole discretion, may apply such unearned sums to payments otherwise due in connection with Institution participation in another Pfizer study or may pursue other available remedies.

2. **Per Subject Cost:** The Per-Subject Cost as defined in Exhibit 1 is based upon completion of all visits and procedures in accordance with the Study specifications set forth in the Protocol. Payments will be calculated based on Study Data entered into EDC system and will be paid as long as the site is in compliance with the Protocol and the terms of the Agreement including the submission of an invoice where required. CRO will make payments on a quarterly basis within forty-five (45) days of completion of each activity period based upon the services completed during the previous three (3) months. The initial activity period will begin on the first day of the month in which the first patient is screened.
3. **Additional Treatment Related Costs:** In addition to the Per-Subject Costs, CRO will pay Institution for the other Additional Treatment Related Costs as set forth in Exhibit 1. Institution shall submit requests for payment for Additional Treatment Related Costs in accordance with **Section 12 (Invoices & Payments)**, including submission of any back-up documentation or receipts for pass-through expenses. Any costs designated as invoiceable in Exhibit 1 should be invoiced at the visits or timepoints specified therein and not submitted to third party insurance payors.
4. **Other Study-Level Costs:** In addition to costs covered in the other two sections of Exhibit 1, CRO will pay Institution for the other Study-Level Costs as set forth in Exhibit 1. Institution shall submit requests for payment for other Study-Level Costs in accordance with **Section 12 (Invoices & Payments)**, including submission of any back-up documentation or receipts for pass-through expenses. Any non-procedural pass-through expenses will be paid only in the amount actually incurred, up to the maximum amounts shown in Exhibit 1, with no mark-up in cost. Any costs designated as invoiceable in Exhibit 1 should be submitted for payment or invoiced, where applicable, at the visits or timepoints specified therein and not submitted to third party insurance payors.
5. **Final Payment:** The final payment will be paid upon final review and acceptance of all Study Data for Study Subjects by CRO, completion of all required administrative matters by the Principal Investigator and/or Institution, including, but not limited to, resolution of



all outstanding queries, and the return of any Pfizer/CRO or Vendor-provided Equipment requested by Pfizer.

6. **No Payment.** Institution will not be paid for any Study Subjects whose enrollment in the Study deviates from the Protocol's eligibility criteria or from whom Study Data cannot be analyzed because of Protocol deviations, lack of proper records or incomplete, uncorrected or unverifiable CRFs.

7. **Investigational Drug:** Per Section 8 of this Agreement, CRO will provide the Pfizer Drug. The following additional Protocol-required drugs will be provided at no charge or Pfizer will cover the costs of as indicated below:

Drug A (lenalidomide) – will be provided by Pfizer

8. **Standard of Care:** Compensation for all Protocol-required activities to be performed by Institution is included in the budget as documented in Exhibit 1.

9. **Screen Failures:** A “Screen Failure” is a consented subject who fails to meet the screening visit criteria and is thus not eligible for enrollment into the Study. Screen Failures will be reimbursed as outlined in Exhibit 1. To receive payment for Screen Failures, the Screening CRFs must be completed. Institution shall request payment for each Screen Failure in accordance with **Section 12 (Invoices & Payments)**, specifying the candidate’s screening number (or other unique identifier) and the date of the Screen Failure.

10. **Patient Travel Expenses:** CRO will reimburse reasonable travel expenses per patient visit during the Study at the rate set out in the Budget (Exhibit 1). Travel reimbursement will be issued directly by Institution to the Study Subjects.

11. **Additional Testing, Treatment or Procedures:** The Parties agree that the Exhibit 1 includes all Trial-related costs, as referenced in the Protocol. Institution will not be reimbursed for any additional testing, treatment, or procedures not required by the Protocol or specified in the Agreement or this Attachment A, unless such additional testing, treatment or procedures are pre-approved by Pfizer or CRO.

12. **Invoices & Payments:**

CRO will make payments within forty-five (45) days of receipt and approval of invoice.

For any costs not in Exhibit 1, requests for payment or reimbursement or invoices must not be submitted by Institution until a contract amendment or a budget modification letter has been executed.

To expedite payment, such invoices can be accompanied by a copy of the amendment.

Invoices must be in the name of CRO and submitted in English. Where hard copy invoices are required they should be submitted and addressed to:



Parexel International Clinical Research Private Limited,
Coworks, Coworking Spaces Pvt.Ltd-RMZ Eco World,
Ground floor, Bay Area- Adjacent to Building 6A,
Outer Ring Road, Devarabeesanahalli Village,
Bengaluru -560103, Karnataka, India

Invoices will be submitted to: Site Monitor

The following information shall be provided when submitting an invoice:

- Invoice number
- Invoice date
- Invoice amount
- Date and description of service provided as described in Exhibit 1
- Principal Investigator Name
- Institution/Center or Site Name and Address
- Pfizer assigned Site Id (as listed above)
- Protocol Identifier or Number
- Tax/VAT Registration Number
- Any Tax/VAT charge, relevant Tax/VAT percentage or indication of a 'reverse charge' as appropriate
- CRO Project Number
- CRO Address (listed above)
- Any other items required by local custom, regulation or law in your jurisdiction.

Failure to include required information on all requests for payment or reimbursement or invoices will result in delayed payment.

13. **Refunds:** To confirm process for return of refunds, Institution shall contact CRO at InvestigatorPaymentHelpDesk@parexel.com or at such other contact as may be communicated from time to time.
14. **Amendments:** The following Study budget changes may be documented by a modification letter signed by Pfizer or its authorized agent: (1) increases in the total Study budget, with or without modification of the payment schedule, or (2) modification of the payment schedule with no change in total Study budget.
15. **Inquiries:** All inquiries regarding the reasons for any denial of, or failure to approve, a request for payment or reimbursement or invoice must be directed to the CRO at InvestigatorPaymentHelpDesk@parexel.com, or such other contact as may be communicated to Institution from time to time.
16. **Research Injury Treatment:** Pursuant to the Indemnification and Research Injury policy, Institution will promptly notify CRO of any Research Injury. Institution will submit all invoices for Research Injury treatment in accordance with **Section 12 (Invoices & Payments)** above.



Invoices for Research Injury treatments must be separate from invoices submitted for any other protocol required treatments or services and be clearly identified as being for a Research Injury treatment. The following information shall be provided when submitting the invoice:

- Invoice number
- Invoice date
- Invoice amount associated with each AE/SAE
- Principal Investigator Name
- Institution/Center or Site Name and Address
- Protocol Identifier or Number
- Subproject Number (if Pfizer supplied)
- Subject Identifier (i.e. as reported on the CRF)
- Date of AE/SAE Onset (i.e. as reported on the CRF)
- AE/SAE treatment(s) associated with each AE/SAE
- Date of treatment(s)
- AE/SAE end date (if not ongoing at the time of invoicing and if consistent with the CRF)
- AE/SAE event term

AE/SAE term(s) and treatment(s) specified in the invoice must match Study Data reported on Case Report Forms and AE/SAE forms to avoid delay in payment.



Exhibit 1 to Attachment A

ARM A

COMPOUND:	PF-06863135	AMENDMENT:	PA2	INVESTIGATOR:	Dr. Sanjay Verma
STUDY NUMBER:	C1071007	ARM/COHORT:	Arm A	INSTITUTION:	Swami Rama Himalayan University
TITLE:	ASPIRE: A RANDOMIZED, 2-ARM, PHASE 3 STUDY OF ELRANATANAB (PF-06863135) VERSUS LENALIDOMIDE IN PATIENTS WITH NEWLY DIAGNOSED MULTIPLE MYELOMA AFTER UNDERGOING AUTOLOGOUS STEM-CELL TRANSPLANTATION				
COUNTRY/Currency:	India - INR	INVESTIGATOR ID:	NA	CCID:	NA
OVERHEAD	20.00%				



Per Subject Cost

DESCRIPTION OF COST	Comments	Frequency of Procedure	Total PSC	VISIT 1		VISIT 2	
				COST	Total Number of times a procedure occurs based on PSC Structure	f	Pre-Screening (Optional)
Informed Consent and distribution of ECC		2,448.00	2.0	4896	1.00	2,448.00	1.00
Demography/medical history		4,000.00	1.0	4000		0.00	1.00
Physical exam	Includes vital signs, height/weight. Includes comprehensive physical exam at screening.	5,800.00	10.5	60900		0.00	1.50
Neurologic exam		5,400.00	16.0	86400		0.00	1.00
ICE Score (Encephalopathy assessment)		5,400.00	1.0	5400		0.00	0.00
Vital signs (temperature, HR, BP and O2 saturation)		1,045.00	19.0	19855		0.00	0.00
ECCG PS		1,045.00	1.0	1045		0.00	1.00
Tricigate 12-Lead ECG		1,500.00	5.0	7500		0.00	0.00
Single 12-Lead ECG		300.00	1.0	300		0.00	1.00
Lab handling and shipping of specimens, complex	for central labs	966.00	12.0	11592		0.00	1.00
SIPEP, SIFE, FLC	Blood draw for central lab	950.00	11.0	10450		0.00	1.00
UEPEP, UIFE	Urine collection for central lab	950.00	11.0	10450		0.00	1.00
Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	Blood draw for central lab	950.00	11.0	10450		0.00	1.00
Hematology	Local Lab	1,050.00	17.0	17850		0.00	1.00
Chemistry	Includes: BUN or Blood Urea, Creatinine, Glucose (non-fasting), Total Calcium, Sodium, Potassium, Chloride, AST, ALT, total bilirubin, Alkaline phosphatase, Albumin. Local lab, Magnesium, Phosphorous or Phosphates	2,060.00	10.0	20600		0.00	1.00
Beta-2 microglobulin	Local Lab	660.00	1.0	660		0.00	1.00
LDH	Local Lab	360.00	6.0	2160		0.00	1.00
Uric Acid	Local Lab	240.00	6.0	1440		0.00	1.00
TSH and reflex testing (T3 or free T3 and free T4)	Local Lab	770.00	4.0	3080		0.00	1.00
PT	Local Lab	300.00	1.0	300		0.00	1.00
INR	Local Lab	300.00	1.0	300		0.00	1.00
Blood sample for PK for eiranatamab		955.00	9.0	8595		0.00	0.00
Blood sample for ADAs and Nabs for eiranatamab		955.00	5.0	4775		0.00	0.00
Blood Sample for sBCMA levels, MRD Tracking, Pfizer Prep D1 retained research samples		955.00	17.0	16235		0.00	2.00
Saliva sample for germline comparator		955.00	1.0	955		0.00	0.00
Study Coordinator - per hour	IRT Registration, Participant ID number, Eligibility criteria, Register with IRT, Randomization, Disease characteristics/treatment history, PROs, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapies, Subsequent anti-cancer therapies/date of progression, survival status, disease	2,453.00	120.8	296322.4	2.50	6,132.50	5.50
Blood Sample for circulating proteins and metabolite analysis, TCR sequencing, and immune cell profiling		955.00	22.0	21010		0.00	1.00
Premedication administration and dispensing for CRS - oral acetaminophen		1,200.00	3.0	3600		0.00	0.00
Eiranatamab administration (injection)		1,303.00	29.0	37787		0.00	0.00
Eiranatamab dispensing (complex)		2,573.00	29.0	74617		0.00	0.00
CMV Testing	Local analysis	2,000.00	1.0	2000		0.00	1.00
	PSC Subtotal w/out Overhead			7,45,524.40		8,580.50	49,805.50
	PSC Subtotal with Overhead			8,94,629.28		10,296.60	59,766.60

263708 C1071007 IND 1284 CSA Verma English 20230411 1.0



DESCRIPTION OF COST	Comments	COST	Frequency of Procedure Total Number of times a procedure occurs based on PSC Structure	VISIT 3		VISIT 4	
				Total PSC	f	C1D1	f
Informed Consent and distribution of ECC		2,448.00	2.0	4896		0.00	0.00
Demography/medical history		4,000.00	1.0	4000		0.00	0.00
Physical exam	Includes vital signs, height/weight. Includes comprehensive physical exam at screening.	5,800.00	10.5	60900	1.00	5,800.00	0.00
Neurologic exam		5,400.00	16.0	86400	1.00	5,400.00	0.00
ICE Score (Encephalopathy assessment)		5,400.00	1.0	5400	1.00	5,400.00	0.00
Vital signs (temperature, HR, BP and O2 saturation)		1,045.00	19.0	19855		0.00	11.00
ECOG PS		1,045.00	1.0	1045		0.00	0.00
Tripleate 12-Lead ECG		1,500.00	5.0	7500	1.00	1,500.00	0.00
Single 12-Lead ECG		300.00	1.0	300		0.00	0.00
Lab handling and shipping of specimens, for central labs complex		966.00	12.0	11592	1.00	966.00	1.00
SPEP, SIFE, FLC	Blood draw for central lab	950.00	11.0	10450	1.00	950.00	0.00
UPEP, UIFE	Urine collection for central lab	950.00	11.0	10450	1.00	950.00	0.00
Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	Blood draw for central lab	950.00	11.0	10450	1.00	950.00	0.00
Hematology	Local Lab	1,050.00	17.0	17850	1.00	1,050.00	0.00
Chemistry	Includes: BUN or Blood Urea, Creatinine, Glucose (non-fasting), Total Calcium, Sodium, Potassium, Chloride, AST, ALT, total bilirubin, Alkaline phosphatase, Albumin. Local lab, Magnesium, Phosphorous or Phosphates	2,060.00	10.0	20600	1.00	2,060.00	0.00
Beta-2 microglobulin	Local Lab	660.00	1.0	660		0.00	0.00
LDH	Local Lab	360.00	6.0	2160	1.00	360.00	1.00
Uric Acid	Local Lab	240.00	6.0	1440	1.00	240.00	1.00
TSH and reflex testing (T3 or free T3 and free T4)	Local Lab	770.00	4.0	3080		0.00	0.00
PT	Local Lab	300.00	1.0	300		0.00	0.00
INR	Local Lab	300.00	1.0	300		0.00	0.00
Blood sample for PK for eranatamab		955.00	9.0	8595	2.00	1,910.00	2.00
Blood sample for ADAs and Nabs for eranatamab		955.00	5.0	4775	1.00	955.00	0.00
Blood Sample for sBCMA levels, MRD Tracking, Pfizer Prep D1 retained research samples		955.00	17.0	16235	3.00	2,865.00	0.00
Saliva sample for germline comparator		955.00	1.0	955	1.00	955.00	0.00
Study Coordinator - per hour	IRT Registration, Participant ID number, Eligibility criteria, Register with IRT, Randomization, Disease characteristics/treatment history, PROs, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapies, Subsequent anti-cancer therapies/date of progression, survival status, disease response assessment per	2,453.00	120.8	296322.4	4.30	10,547.80	3.20
							7,849.60
Blood Sample for circulating proteins and metabolite analysis, TCR sequencing, and immune cell profiling		955.00	22.0	21010	3.00	2,865.00	2.00
Premedication administration and dispensing for CRS - oral acetaminophen		1,200.00	3.0	3600	1.00	1,200.00	1.00
Eranatamab administration (injector)		1,303.00	29.0	37787	1.00	1,303.00	1.00
Eranatamab dispensing (complex)		2,573.00	29.0	74617	1.00	2,573.00	1.00
CMV Testing	Local analysis	2,000.00	1.0	2000		0.00	0.00
	PSC Subtotal w/out Overhead			7,45,524.40		50,799.60	
	PSC Subtotal with Overhead			8,94,629.28		60,959.88	
							35,767.92



DESCRIPTION OF COST	Comments	COST	Frequency of Procedure Total Number of times a procedure occurs based on PSC Structure	VISIT 5		VISIT 6		VISIT 7	
				Total PSC	f	C1D8	f	C1D15	f
Informed Consent and distribution of ECC		2,448.00	2.0	4896		0.00	0.00		0.00
Demography/medical history		4,000.00	1.0	4000		0.00	0.00		0.00
Physical exam	Includes vital signs, height/weight. Includes comprehensive physical exam at screening.	5,800.00	10.5	60900		0.00	0.60		0.00
Neurologic exam		5,400.00	16.0	86400		0.00	1.00	5,400.00	0.00
ICE Score (Encephalopathy assessment)		5,400.00	1.0	5400		0.00	0.00		0.00
Vital signs (temperature, HR, BP and O ₂ saturation)		1,045.00	19.0	19855	6.00	6,270.00	1.00	1,045.00	1.00
ECOG PS		1,045.00	1.0	1045		0.00	0.00		0.00
Tricigate 12-Lead ECG		1,500.00	5.0	7500	1.00	1,500.00	0.00		0.00
Single 12-Lead ECG		300.00	1.0	300		0.00	0.00		0.00
Lab handling and shipping of specimens, complex	for central labs	966.00	12.0	11592	1.00	966.00	1.00	966.00	0.00
SPEP, SIFE, FLC	Blood draw for central lab	950.00	11.0	10450		0.00	0.00		0.00
UPEP, UFE	Urine collection for central lab	950.00	11.0	10450		0.00	0.00		0.00
Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	Blood draw for central lab	950.00	11.0	10450		0.00	0.00		0.00
Hematology	Local Lab	1,050.00	17.0	17850	1.00	1,050.00	1.00	1,050.00	1.00
Chemistry	Includes: BUN or Blood Urea, Creatinine, Glucose (non-fasting), Total Calcium, Sodium, Potassium, Chloride, AST, ALT, total bilirubin, Alkaline phosphatase, Albumin. Local lab, Magnesium, Phosphorous or Phosphates	2,060.00	10.0	20600		0.00	0.00		0.00
Beta-2 microglobulin	Local Lab	660.00	1.0	660		0.00	0.00		0.00
LDH	Local Lab	360.00	6.0	2160	1.00	360.00	1.00	360.00	1.00
Uric Acid	Local Lab	240.00	6.0	1440	1.00	240.00	1.00	240.00	1.00
TSH and reflex testing (T3 or free T3 and free T4)	Local Lab	770.00	4.0	3080		0.00	0.00		0.00
PT	Local Lab	300.00	1.0	300		0.00	0.00		0.00
INR	Local Lab	300.00	1.0	300		0.00	0.00		0.00
Blood sample for PK for elanatamab		955.00	9.0	8595	1.00	955.00		0.00	0.00
Blood sample for ADAs and Nabs for elanatamab		955.00	5.0	4775		0.00	0.00		0.00
Blood Sample for sBCMA levels, MRD Tracking, Pfizer Prep D1 retained research samples		955.00	17.0	16235	1.00	955.00		0.00	0.00
Saliva sample for germline comparator		955.00	1.0	955		0.00	0.00		0.00
Study Coordinator - per hour	IRT Registration, Participant ID number, Eligibility criteria, Register with IRT, Randomization, Disease characteristics/treatment history, PROs, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapies, Subsequent anti-cancer therapies/date of progression, survival status, disease response assessment per	2,453.00	120.8	296322.4	3.20	7,849.60	3.70	9,075.10	3.20
Blood Sample for circulating proteins and metabolite analysis, TCR sequencing, and immune cell profiling		955.00	22.0	21010	2.00	1,910.00	3.00	2,865.00	0.00
Premedication administration and dispensing for CRS - oral acetaminophen		1,200.00	3.0	3600	1.00	1,200.00		0.00	0.00
Elanatamab administration (injection)		1,303.00	29.0	37787	1.00	1,303.00	1.00	1,303.00	1.00
Elanatamab dispensing (complex)		2,573.00	29.0	74617	1.00	2,573.00	1.00	2,573.00	1.00
CMV Testing	Local analysis	2,000.00	1.0	2000		0.00	0.00		0.00
	PSC Subtotal w/out Overhead			7,45,524.40		27,131.60		24,678.10	14,420.60
	PSC Subtotal with Overhead			8,94,629.28		32,557.92		29,853.72	17,304.72



DESCRIPTION OF COST	Comments	COST	Frequency of Procedure Total Number of times a procedure occurs based on PSC Structure	Total PSC	VISIT 8		VISIT 9		VISIT 10	
					f	C2D1	f	C2D8	f	C2D15
Informed Consent and distribution of ECC		2,448.00	2.0	4896		0.00		0.00		0.00
Demography/medical history		4,000.00	1.0	4000		0.00		0.00		0.00
Physical exam	Includes vital signs, height/weight. Includes comprehensive physical exam at screening.	5,800.00	10.5	60900	1.00	5,800.00		0.00		0.00
Neurologic exam		5,400.00	16.0	86400	1.00	5,400.00		0.00	1.00	5,400.00
ICE Score (Encephalopathy assessment)		5,400.00	1.0	5400		0.00		0.00		0.00
Vital signs (temperature, HR, BP and O2 saturation)		1,045.00	19.0	19855		0.00		0.00		0.00
ECOG PS		1,045.00	1.0	1045		0.00		0.00		0.00
Triphasic 12-Lead ECG		1,500.00	5.0	7500	1.00	1,500.00		0.00		0.00
Single 12-Lead ECG		300.00	1.0	300		0.00		0.00		0.00
Lab handling and shipping of specimens, complex	for central labs	966.00	12.0	11592	1.00	966.00		0.00		0.00
SEPE, SIFE, FLC	Blood draw for central lab	950.00	11.0	10450	1.00	950.00		0.00		0.00
UPEP, UIFE	Urine collection for central lab	950.00	11.0	10450	1.00	950.00		0.00		0.00
Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	Blood draw for central lab	950.00	11.0	10450	1.00	950.00		0.00		0.00
Hematology	Local Lab	1,050.00	17.0	17850	1.00	1,050.00	1.00	1,050.00	1.00	1,050.00
Chemistry	Includes: BUN or Blood Urea, Creatinine, Glucose (non-fasting), Total Calcium, Sodium, Potassium, Chloride, AST, ALT, total bilirubin, Alkaline phosphatase, Albumin, Local lab, Magnesium, Phosphorous or Phosphates	2,060.00	10.0	20600	1.00	2,060.00		0.00		0.00
Beta-2 microglobulin	Local Lab	660.00	1.0	660		0.00		0.00		0.00
LDH	Local Lab	360.00	6.0	2160		0.00		0.00		0.00
Uric Acid	Local Lab	240.00	6.0	1440		0.00		0.00		0.00
TSH and reflex testing (T3 or free T3 and free T4)	Local Lab	770.00	4.0	3080		0.00		0.00		0.00
PT	Local Lab	300.00	1.0	300		0.00		0.00		0.00
INR	Local Lab	300.00	1.0	300		0.00		0.00		0.00
Blood sample for PK for elanatamab		955.00	9.0	8595	1.00	955.00		0.00		0.00
Blood sample for ADAs and Nabs for elanatamab		955.00	5.0	4775	1.00	955.00		0.00		0.00
Blood Sample for BCMA levels, NFD Tracking, Pfizer Prep D1 retained research samples		955.00	17.0	16235	2.00	1,910.00		0.00		0.00
Saliva sample for germline comparator		955.00	1.0	955		0.00		0.00		0.00
Study Coordinator - per hour	IRT Registration, Participant ID number, Eligibility criteria, Register with IRT, Randomization, Disease characteristics/treatment history, PROs, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapies, Subsequent anti-cancer therapies/date of progression, survival status, disease response assessment per	2,453.00	120.8	296322.4	4.30	10,547.90	3.20	7,849.60	3.20	7,849.60
Blood Sample for circulating proteins and metabolic analysis, TCR sequencing, and immune cell profiling		955.00	22.0	21010	2.00	1,910.00		0.00		0.00
Premedication administration and dispensing for CRS - oral acetaminophen		1,200.00	3.0	3600		0.00		0.00		0.00
Elanatamab administration (injection)		1,303.00	29.0	37787	1.00	1,303.00	1.00	1,303.00	1.00	1,303.00
Elanatamab dispensing (complex)		2,573.00	29.0	74617	1.00	2,573.00	1.00	2,573.00	1.00	2,573.00
CMV Testing	Local analysis	2,000.00	1.0	2000		0.00		0.00		0.00
				PSC Subtotal w/out Overhead		7,45,524.40		39,779.90		12,775.60
				PSC Subtotal with Overhead		8,94,629.28		47,735.88		15,330.72
										21,810.72



DESCRIPTION OF COST	Comments	COST	Frequency of Procedure Total Number of times a procedure occurs based on PSC Structure	VISIT 11		VISIT 12		VISIT 13		
				Total PSC	f	C2D22	f	C3D1	f	C3D8
Informed Consent and distribution of ECC		2,446.00	2.0	4896		0.00		0.00		0.00
Demography/medical history		4,000.00	1.0	4000		0.00		0.00		0.00
Physical exam	Includes vital signs, height/weight. Includes comprehensive physical exam at screening	5,800.00	10.5	60900		0.00	1.00	5,800.00		0.00
Neurologic exam		5,400.00	15.0	86400		0.00	1.00	5,400.00		0.00
ICE Score (Encephalopathy assessment)		5,400.00	1.0	5400		0.00		0.00		0.00
Vital signs (temperature, HR, BP and O2 saturation)		1,045.00	19.0	19855		0.00		0.00		0.00
ECOG PS		1,045.00	1.0	1045		0.00		0.00		0.00
Tricigate 12-Lead ECG		1,500.00	5.0	7500		0.00		0.00		0.00
Single 12-Lead ECG		300.00	1.0	300		0.00		0.00		0.00
Lab handling and shipping of specimens, complex	for central labs	966.00	12.0	11592		0.00	1.00	966.00		0.00
SPEP, SIFE, FLC	Blood draw for central lab	950.00	11.0	10450		0.00	1.00	950.00		0.00
UEEP, UIFE	Urine collection for central lab	950.00	11.0	10450		0.00	1.00	950.00		0.00
Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	Blood draw for central lab	950.00	11.0	10450		0.00	1.00	950.00		0.00
Hematology	Local Lab	1,050.00	17.0	17850	1.00	1,050.00	1.00	1,050.00		0.00
Chemistry	Includes: BUN or Blood Urea, Creatinine, Glucose (non-fasting), Total Calcium, Sodium, Potassium, Chloride, AST, ALT, total bilirubin, Alkaline phosphatase, Albumin, Local lab, Magnesium, Phosphorous or Phosphates	2,060.00	10.0	20600		0.00	1.00	2,060.00		0.00
Beta-2 microglobulin	Local Lab	660.00	1.0	660		0.00		0.00		0.00
LDH	Local Lab	360.00	6.0	2160		0.00		0.00		0.00
Uric Acid	Local Lab	240.00	6.0	1440		0.00		0.00		0.00
TSH and reflex testing (T3 or free T3 and free T4)	Local Lab	770.00	4.0	3080		0.00		0.00		0.00
PT	Local Lab	300.00	1.0	300		0.00		0.00		0.00
INR	Local Lab	300.00	1.0	300		0.00		0.00		0.00
Blood sample for PK for elanatamab		955.00	9.0	8595		0.00		0.00		0.00
Blood sample for ADAs and Nabs for elanatamab		955.00	5.0	4775		0.00		0.00		0.00
Blood Sample for BCMA levels, MRD Tracking, Pfizer Prep D1 retained research samples		955.00	17.0	16235		0.00	1.00	955.00		0.00
Saliva sample for germline comparator		955.00	1.0	955		0.00		0.00		0.00
Study Coordinator - per hour	IRT Registration, Participant ID number, Eligibility criteria, Register with IRT, Randomization, Disease characteristics/treatment history, PROs, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapies, Subsequent anti-cancer therapies/date of progression, survival status, disease response assessment per	2,453.00	120.8	296322.4	3.20	7,849.60	4.30	10,547.90	3.20	7,849.60
Blood Sample for circulating proteins and metabolite analysis, TCR sequencing, and immune cell profiling		855.00	22.0	21010		0.00	3.00	2,865.00		0.00
Premedication administration and dispensing for CRS - oral acetaminophen		1,200.00	3.0	3600		0.00		0.00		0.00
Elanatamab administration (injection)		1,303.00	29.0	37787	1.00	1,303.00	1.00	1,303.00	1.00	1,303.00
Elanatamab dispensing (complex)		2,573.00	29.0	74617	1.00	2,573.00	1.00	2,573.00	1.00	2,573.00
CMV Testing	Local analysis	2,000.00	1.0	2000		0.00		0.00		0.00
	PSC Subtotal w/out Overhead			7,45,524.40		12,775.60		36,369.90		11,725.60
	PSC Subtotal with Overhead			8,84,629.28		15,330.72		43,643.88		14,070.72



DESCRIPTION OF COST	Comments	COST	Frequency of Procedure Total Number of times a procedure occurs based on PSC Structure	VISIT 14		VISIT 15		VISIT 16	
				Total PSC	f	C3D15	f	C3D22	f
Informed Consent and distribution of ECC		2,448.00	2.0	4896		0.00		0.00	
Demography/medical history		4,000.00	1.0	4000		0.00		0.00	
Physical exam	Includes vital signs, height/weight. Includes comprehensive physical exam at screening.	5,800.00	10.5	60900		0.00		0.00	1.00
Neurologic exam		5,400.00	16.0	86400	1.00	5,400.00		0.00	1.00
ICE Score (Encephalopathy assessment)		5,400.00	1.0	5400		0.00		0.00	
Vital signs (temperature, HR, BP and O2 saturation)		1,045.00	19.0	19855		0.00		0.00	
ECOG PS		1,045.00	1.0	1045		0.00		0.00	
Truplicate 12-Lead ECG		1,500.00	5.0	7500		0.00		0.00	1.00
Single 12-Lead ECG		300.00	1.0	300		0.00		0.00	
Lab handling and shipping of specimens, for central labs		966.00	12.0	11592		0.00		0.00	1.00
SPEP, SIFE, FLC	Blood draw for central lab	950.00	11.0	10450		0.00		0.00	1.00
UPEP, UIFE	Urine collection for central lab	950.00	11.0	10450		0.00		0.00	1.00
Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	Blood draw for central lab	950.00	11.0	10450		0.00		0.00	1.00
Hematology	Local Lab	1,050.00	17.0	17850	1.00	1,050.00		0.00	1.00
Chemistry	Includes: BUN or Blood Urea, Creatinine, Glucose (non-fasting), Total Calcium, Sodium, Potassium, Chloride, AST, ALT, total bilirubin, Alkaline phosphatase, Albumin. Local lab, Magnesium, Phosphorous or Phosphates	2,050.00	10.0	20600		0.00		0.00	1.00
Beta-2 microglobulin	Local Lab	660.00	1.0	660		0.00		0.00	
LDH	Local Lab	360.00	6.0	2160		0.00		0.00	
Uric Acid	Local Lab	240.00	6.0	1440		0.00		0.00	
TSH and reflex testing (T3 or free T3 and free T4)	Local Lab	770.00	4.0	3080		0.00		0.00	1.00
PT	Local Lab	300.00	1.0	300		0.00		0.00	
INR	Local Lab	300.00	1.0	300		0.00		0.00	
Blood sample for PK for elranatamab		955.00	9.0	8595		0.00		0.00	1.00
Blood sample for ADAs and Nabs for elranatamab		955.00	5.0	4775		0.00		0.00	1.00
Blood Sample for sBCMA levels, MRD Tracking, Pfizer Prep D1 retained research samples		955.00	17.0	16235		0.00		0.00	2.00
Saliva sample for germline comparador		955.00	1.0	955		0.00		0.00	
Study Coordinator - per hour	IRT Registration, Participant ID number, Eligibility criteria, Register with IRT, Randomization, Disease characteristics/treatment history, PROs, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapies, Subsequent anti-cancer therapies/date of progression, survival status, disease response assessment per	2,453.00	120.8	295322.4	3.70	9,076.10	3.20	7,849.60	4.30
Blood Sample for circulating proteins and metabolite analysis, TCR sequencing, and immune cell profiling		955.00	22.0	21010		0.00		0.00	1.00
Premedication administration and dispensing for CRS - oral acetaminophen		1,200.00	3.0	3600		0.00		0.00	
Elranatamab administration (injection)		1,303.00	29.0	37787	1.00	1,303.00	1.00	1,303.00	1.00
Elranatamab dispensing (complex)		2,573.00	29.0	74617	1.00	2,573.00	1.00	2,573.00	1.00
CMV Testing	Local analysis	2,000.00	1.0	2000		0.00		0.00	
	PSC Subtotal w/out Overhead			7,45,524.40		19,402.10		11,725.60	
	PSC Subtotal with Overhead			8,94,629.28		23,282.52		14,070.72	
									47,513.88



DESCRIPTION OF COST	Comments	COST	Frequency of Procedure Total Number of times a procedure occurs based on PSC Structure	VISIT 17		VISIT 18		VISIT 19		
				Total PSC	f	C4D8	f	C4D15	f	C4D22
Informed Consent and distribution of ECC		2,448.00	2.0	4896		0.00		0.00		0.00
Demography/medical history		4,000.00	1.0	4000		0.00		0.00		0.00
Physical exam	Includes vital signs, height/weight. Includes comprehensive physical exam at screening.	5,800.00	10.5	60900		0.00		0.00		0.00
Neurologic exam		5,400.00	16.0	86400		0.00	1.00	5,400.00		0.00
ICE Score (Encephalopathy assessment)		5,400.00	1.0	5400		0.00		0.00		0.00
Vital signs (temperature, HR, BP and O2 saturation)		1,045.00	19.0	19855		0.00		0.00		0.00
ECOG PS		1,045.00	1.0	1045		0.00		0.00		0.00
Trilead 12-Lead ECG		1,500.00	5.0	7500		0.00		0.00		0.00
Single 12-Lead ECG		300.00	1.0	300		0.00		0.00		0.00
Lab handling and shipping of specimens, for central labs complex		956.00	12.0	11562		0.00		0.00		0.00
SPEP, SIFE, FLC	Blood draw for central lab	950.00	11.0	10450		0.00		0.00		0.00
UPEP, UIFE	Urine collection for central lab	950.00	11.0	10450		0.00		0.00		0.00
Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	Blood draw for central lab	950.00	11.0	10450		0.00		0.00		0.00
Hematology	Local Lab	1,050.00	17.0	17850		0.00		0.00		0.00
Chemistry	Includes: BUN or Blood Urea, Creatinine, Glucose (non-fasting). Total Calcium, Sodium, Potassium, Chloride, AST, ALT, total bilirubin, Alkaline phosphatase, Albumin. Local lab, Magnesium, Phosphorous or Phosphates	2,050.00	10.0	20600		0.00		0.00		0.00
Beta-2 microglobulin	Local Lab	660.00	1.0	660		0.00		0.00		0.00
LDH	Local Lab	360.00	6.0	2160		0.00		0.00		0.00
Uric Acid	Local Lab	240.00	6.0	1440		0.00		0.00		0.00
TSH and reflex testing (T3 or free T3 and free T4)	Local Lab	770.00	4.0	3080		0.00		0.00		0.00
PT	Local Lab	300.00	1.0	300		0.00		0.00		0.00
INR	Local Lab	300.00	1.0	300		0.00		0.00		0.00
Blood sample for PK for elranatamab		955.00	9.0	8595		0.00		0.00		0.00
Blood sample for ADAs and Nabs for elranatamab		955.00	5.0	4775		0.00		0.00		0.00
Blood Sample for sBCMA levels, MRD Tracking, Pfizer Prep D1 retained research samples		955.00	17.0	16235		0.00		0.00		0.00
Saliva sample for germline comparator		955.00	1.0	955		0.00		0.00		0.00
Study Coordinator - per hour	IRT Registration, Participant ID number, Eligibility criteria, Register with IRT, Randomization, Disease characteristics/treatment history, PROs, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapies, Subsequent anti-cancer therapies/date of progression, survival status, disease response assessment per	2,453.00	120.8	296322.4	3.20	7,849.60	3.70	8,076.10	3.20	7,849.60
Blood Sample for circulating proteins and metabolite analysis, TCR sequencing, and immune cell profiling		955.00	22.0	21010		0.00		0.00		0.00
Premedication administration and dispensing for CRS - oral acetaminophen		1,200.00	3.0	3600		0.00		0.00		0.00
Elranatamab administration (injection)		1,303.00	29.0	37787	1.00	1,303.00	1.00	1,303.00	1.00	1,303.00
Elranatamab dispensing (complex)		2,573.00	29.0	74617	1.00	2,573.00	1.00	2,573.00	1.00	2,573.00
CMV Testing	Local analysis	2,000.00	1.0	2000		0.00		0.00		0.00
	PSC Subtotal w/out Overhead			7,45,524.40		11,725.60		18,352.10		11,725.60
	PSC Subtotal with Overhead			8,54,629.28		14,070.72		22,022.52		14,070.72



DESCRIPTION OF COST	Comments	COST	Frequency of Procedure	Total Number of times a procedure occurs based on PSC Structure	VISIT 20		VISIT 21		VISIT 22		
					Total PSC	f	C5D1	f	C5D8	f	C5D15
Informed Consent and distribution of ECC		2,448.00	2.0	4896		0.00		0.00		0.00	
Demography/medical history		4,000.00	1.0	4000		0.00		0.00		0.00	
Physical exam	Includes vital signs, height/weight. Includes comprehensive physical exam at screening.	5,800.00	10.5	60900	1.00	5,800.00		0.00		0.00	
Neurologic exam		5,400.00	16.0	66400	1.00	5,400.00		0.00	1.00	5,400.00	
ICE Score (Encephalopathy assessment)		5,400.00	1.0	5400		0.00		0.00		0.00	
Vital signs (temperature, HR, BP and O2 saturation)		1,045.00	19.0	19855		0.00		0.00		0.00	
ECOG PS		1,045.00	1.0	1045		0.00		0.00		0.00	
Tricotate 12-Lead ECG		1,500.00	5.0	7500		0.00		0.00		0.00	
Single 12-Lead ECG		300.00	1.0	300		0.00		0.00		0.00	
Lab handling and shipping of specimens, for central labs complex		996.00	12.0	11592	1.00	996.00		0.00		0.00	
SPEP, SIFE, FLC	Blood draw for central lab	950.00	11.0	10450	1.00	950.00		0.00		0.00	
UPEP, UFE	Urine collection for central lab	950.00	11.0	10450	1.00	950.00		0.00		0.00	
Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	Blood draw for central lab	950.00	11.0	10450	1.00	950.00		0.00		0.00	
Hematology	Local Lab	1,050.00	17.0	17850	1.00	1,050.00		0.00		0.00	
Chemistry	Includes: BUN or Blood Urea, Creatinine, Glucose (non-fasting), Total Calcium, Sodium, Potassium, Chloride, AST, ALT, total bilirubin, Alkaline phosphatase, Albumin. Local lab, Magnesium, Phosphorous or Phosphates	2,060.00	10.0	20600	1.00	2,060.00		0.00		0.00	
Beta-2 microglobulin	Local Lab	660.00	1.0	660		0.00		0.00		0.00	
LDH	Local Lab	360.00	6.0	2160		0.00		0.00		0.00	
Uric Acid	Local Lab	240.00	6.0	1440		0.00		0.00		0.00	
TSH and reflex testing (T3 or free T3 and free T4)	Local Lab	770.00	4.0	3080		0.00		0.00		0.00	
PT	Local Lab	300.00	1.0	300		0.00		0.00		0.00	
INR	Local Lab	300.00	1.0	300		0.00		0.00		0.00	
Blood sample for PK for eranatamab		955.00	9.0	8595		0.00		0.00		0.00	
Blood sample for ADAs and Nabs for eranatamab		955.00	5.0	4775		0.00		0.00		0.00	
Blood Sample for sBCMA levels, MRD Tracking, Pfizer Prep D1 retained research samples		955.00	17.0	16235	1.00	955.00		0.00		0.00	
Saliva sample for germline comparator		955.00	1.0	955		0.00		0.00		0.00	
Study Coordinator - per hour	IRT Registration, Participant ID number, Eligibility criteria, Register with IRT, Randomization, Disease characteristics/treatment history, PROs, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapies, Subsequent anti-cancer therapies/date of progression, survival status, disease response assessment per	2,453.00	120.8	296322.4	4.30	10,547.90	3.20	7,849.60	3.70	9,076.10	
Blood Sample for circulating proteins and metabolite analysis, TCR sequencing, and immune cell profiling		955.00	22.0	21010	1.00	955.00		0.00		0.00	
Premedication administration and dispensing for CRS - oral acetaminophen		1,200.00	3.0	3600		0.00		0.00		0.00	
Eranatamab administration (injection)		1,303.00	29.0	37787	1.00	1,303.00	1.00	1,303.00	1.00	1,303.00	
Eranatamab dispensing (complex)		2,573.00	29.0	74617	1.00	2,573.00	1.00	2,573.00	1.00	2,573.00	
CMV Testing	Local analysis	2,000.00	1.0	2000		0.00		0.00		0.00	
				PSC Subtotal w/out Overhead		7,45,524.40		34,459.90		11,725.60	
				PSC Subtotal with Overhead		8,94,629.28		41,351.88		14,070.72	
										22,022.52	



DESCRIPTION OF COST	Comments	COST	Frequency of Procedure Total Number of times a procedure occurs based on PSC Structure	VISIT 23		VISIT 24		VISIT 25		
				Total PSC	f	C5D22	f	C6D1	f	C6D8
Informed Consent and distribution of ECC		2,448.00	2.0	4896		0.00		0.00		0.00
Demography/medical history		4,000.00	1.0	4000		0.00		0.00		0.00
Physical exam	Includes vital signs, height/weight. Includes comprehensive physical exam at screening.	5,800.00	10.5	60500		0.00	1.00	5,800.00		0.00
Neurologic exam		5,400.00	16.0	86400		0.00	1.00	5,400.00		0.00
ICE Score (Encephalopathy assessment)		5,400.00	1.0	5400		0.00		0.00		0.00
Vital signs (temperature, HR, BP and O2 saturation)		1,045.00	19.0	19855		0.00		0.00		0.00
ECOG PS		1,045.00	1.0	1045		0.00		0.00		0.00
Triplex 12-Lead ECG		1,500.00	5.0	7500		0.00		0.00		0.00
Single 12-Lead ECG		300.00	1.0	300		0.00		0.00		0.00
Lab handling and shipping of specimens, complex	for central labs	966.00	12.0	11502		0.00	1.00	966.00		0.00
SPEP, SIFE, FLC	Blood draw for central lab	950.00	11.0	10450		0.00	1.00	950.00		0.00
UPEP, UIFE	Urine collection for central lab	950.00	11.0	10450		0.00	1.00	950.00		0.00
Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	Blood draw for central lab	950.00	11.0	10450		0.00	1.00	950.00		0.00
Hematology	Local Lab	1,050.00	17.0	17850		0.00	1.00	1,050.00		0.00
Chemistry	Includes: BUN or Blood Urea, Creatinine, Glucose (non-fasting), Total Calcium, Sodium, Potassium, Chloride, AST, ALT, total bilirubin, Alkaline phosphatase, Albumin. Local lab, Magnesium, Phosphorus or Phosphates	2,060.00	10.0	20600		0.00	1.00	2,060.00		0.00
Beta-2 microglobulin	Local Lab	660.00	1.0	660		0.00		0.00		0.00
LDH	Local Lab	360.00	6.0	2160		0.00		0.00		0.00
Uric Acid	Local Lab	240.00	6.0	1440		0.00		0.00		0.00
TSH and reflex testing (T3 or free T3 and free T4)	Local Lab	770.00	4.0	3080		0.00		0.00		0.00
PT	Local Lab	300.00	1.0	300		0.00		0.00		0.00
INR	Local Lab	300.00	1.0	300		0.00		0.00		0.00
Blood sample for PK for elanatamab		955.00	9.0	8595		0.00		0.00		0.00
Blood sample for ADAs and Nabs for elanatamab		955.00	5.0	4775		0.00		0.00		0.00
Blood Sample for sBCMA levels, MRD Tracking, Pfizer Prep D1 retained research samples		955.00	17.0	16235		0.00	1.00	955.00		0.00
Saliva sample for germline comparator		955.00	1.0	955		0.00		0.00		0.00
Study Coordinator - per hour	IRT Registration, Participant ID number, Eligibility criteria, Register with IRT, Randomization, Disease characteristics/treatment history, PROs, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapies, Subsequent anti-cancer therapies/date of progression, survival status, disease response assessment per	2,453.00	120.8	296322.4	3.20	7,849.60	4.30	10,547.90	3.20	7,849.60
Blood Sample for circulating proteins and metabolite analysis, TCR sequencing, and immune cell profiling		955.00	22.0	21010		0.00	1.00	955.00		0.00
Premedication administration and dispensing for CRS - oral acetaminophen		1,200.00	3.0	3600		0.00		0.00		0.00
Elanatamab administration (injection)		1,303.00	29.0	37787	1.00	1,303.00	1.00	1,303.00	1.00	1,303.00
Elanatamab dispensing (complex)		2,573.00	29.0	74617	1.00	2,573.00	1.00	2,573.00	1.00	2,573.00
CMV Testing	Local analysis	2,000.00	1.0	2000		0.00		0.00		0.00
	PSC Subtotal w/out Overhead			7,45,524.40		11,725.60		34,459.90		11,725.60
	PSC Subtotal with Overhead			8,94,625.28		14,070.72		41,351.88		14,070.72



DESCRIPTION OF COST	Comments	COST	Frequency of Procedure	Total PSC	VISIT 26		VISIT 27		VISIT 28	
					f	C6D15	f	C6D22	f	C7D1
Informed Consent and distribution of ECC		2,448.00	2.0	4896		0.00		0.00		0.00
Demography/medical history		4,000.00	1.0	4000		0.00		0.00		0.00
Physical exam	Includes vital signs, height/weight. Includes comprehensive physical exam at screening.	5,800.00	10.5	60900		0.00		0.00	1.00	5,800.00
Neurologic exam		5,400.00	16.0	86400	1.00	5,400.00		0.00	1.00	5,400.00
ICE Score (Encephalopathy assessment)		5,400.00	1.0	5400		0.00		0.00		0.00
Vital signs (temperature, HR, BP and O ₂ saturation)		1,045.00	19.0	19855		0.00		0.00		0.00
ECOG PS		1,045.00	1.0	1045		0.00		0.00		0.00
Triphasic 12-Lead ECG		1,500.00	5.0	7500		0.00		0.00		0.00
Single 12-Lead ECG		300.00	1.0	300		0.00		0.00		0.00
Lab handling and shipping of specimens, complex	for central labs	966.00	12.0	11592		0.00		0.00	1.00	966.00
SFEP, SIFE, FLC	Blood draw for central lab	950.00	11.0	10450		0.00		0.00	1.00	950.00
UPEP, UFE	Urine collection for central lab	950.00	11.0	10450		0.00		0.00	1.00	950.00
Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	Blood draw for central lab	950.00	11.0	10450		0.00		0.00	1.00	950.00
Hematology	Local Lab	1,050.00	17.0	17850		0.00		0.00	1.00	1,050.00
Chemistry	Includes: BUN or Blood Urea, Creatinine, Glucose (non-fasting), Total Calcium, Sodium, Potassium, Chloride, AST, ALT, total bilirubin, Alkaline phosphatase, Albumin. Local lab, Magnesium, Phosphorous or Phosphates	2,060.00	10.0	20600		0.00		0.00	1.00	2,060.00
Beta-2 microglobulin	Local Lab	660.00	1.0	660		0.00		0.00		0.00
LDH	Local Lab	360.00	6.0	2160		0.00		0.00		0.00
Uric Acid	Local Lab	240.00	6.0	1440		0.00		0.00		0.00
TSH and reflex testing (T3 or free T3 and free T4)	Local Lab	770.00	4.0	3080		0.00		0.00	1.00	770.00
PT	Local Lab	300.00	1.0	300		0.00		0.00		0.00
INR	Local Lab	300.00	1.0	300		0.00		0.00		0.00
Blood sample for PK for ekananatamab		955.00	9.0	8595		0.00		0.00	1.00	855.00
Blood sample for ADAs and Nabs for ekananatamab		955.00	5.0	4775		0.00		0.00	1.00	955.00
Blood Sample for sBCMA levels, MRD Tracking, Pfizer Prep D1 retained research samples		955.00	17.0	16235		0.00		0.00	2.00	1,910.00
Saliva sample for germline comparator		955.00	1.0	955		0.00		0.00		0.00
Study Coordinator - per hour	IRT Registration, Participant ID number, Eligibility criteria, Register with IRT. Randomization, Disease characteristics/treatment history, PROs, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapies, Subsequent anti-cancer therapies/date of progression, survival status, disease response assessment per	2,453.00	120.8	296322.4	3.70	9,076.10	3.20	7,849.60	4.30	10,547.90
Blood Sample for circulating proteins and metabolite analysis, TCR sequencing, and immune cell profiling		955.00	22.0	21010		0.00		0.00	1.00	955.00
Premedication administration and dispensing for CRS - oral acetaminophen		1,200.00	3.0	3600		0.00		0.00		0.00
Ekananatamab administration (injection)		1,303.00	29.0	37787	1.00	1,303.00	1.00	1,303.00	1.00	1,303.00
Ekananatamab dispensing (complex)		2,573.00	29.0	74617	1.00	2,573.00	1.00	2,573.00	1.00	2,573.00
CMV Testing	Local analysis	2,000.00	1.0	2000		0.00		0.00		0.00
	PSC Subtotal w/out Overhead			7,45,524.40		18,352.10		11,725.60		38,094.90
	PSC Subtotal with Overhead			8,94,629.28		22,022.52		14,070.72		45,713.88



DESCRIPTION OF COST	Comments	COST	Frequency of Procedure Total Number of times a procedure occurs based on PSC Structure	VISIT 29		VISIT 30		VISIT 31		
				Total PSC	f	C7D8	f	C7D15	f	C7D22
Informed Consent and distribution of ECC		2,448.00	2.0	4896		0.00		0.00		0.00
Demography/medical history		4,000.00	1.0	4000		0.00		0.00		0.00
Physical exam	Includes vital signs, height/weight. Includes comprehensive physical exam at screening.	5,800.00	10.5	60900		0.00		0.00		0.00
Neurologic exam		5,400.00	16.0	88400		0.00		0.00		0.00
ICE Score (Encephalopathy assessment)		5,400.00	1.0	5400		0.00		0.00		0.00
Vital signs (temperature, HR, BP and O2 saturation)		1,045.00	19.0	19855		0.00		0.00		0.00
ECOG PS		1,045.00	1.0	1045		0.00		0.00		0.00
Triplicate 12-Lead ECG		1,500.00	5.0	7500		0.00		0.00		0.00
Single 12-Lead ECG		300.00	1.0	300		0.00		0.00		0.00
Lab handling and shipping of specimens, for central labs complex		966.00	12.0	11592		0.00		0.00		0.00
SPEP, SIFE, FLC	Blood draw for central lab	950.00	11.0	10450		0.00		0.00		0.00
UPEP, UFE	Urine collection for central lab	950.00	11.0	10450		0.00		0.00		0.00
Serum quantitative immunoglobulins (IgG, IgM, IgD, IgE)	Blood draw for central lab	950.00	11.0	10450		0.00		0.00		0.00
Hematology	Local Lab	1,050.00	17.0	17850		0.00		0.00		0.00
Chemistry	Includes: BUN or Blood Urea, Creatinine, Glucose (non-fasting), Total Calcium, Sodium, Potassium, Choline, AST, ALT, total bilirubin, Alkaline phosphatase, Alkaline Phosphatase, Magnesium, Phosphorous or Phosphates	2,060.00	10.0	20600		0.00		0.00		0.00
Beta-2 microglobulin	Local Lab	660.00	1.0	660		0.00		0.00		0.00
LDH	Local Lab	360.00	6.0	2160		0.00		0.00		0.00
Uric Acid	Local Lab	240.00	6.0	1440		0.00		0.00		0.00
TSH and reflex testing (T3 or free T3 and free T4)	Local Lab	770.00	4.0	3080		0.00		0.00		0.00
PT	Local Lab	300.00	1.0	300		0.00		0.00		0.00
INR	Local Lab	300.00	1.0	300		0.00		0.00		0.00
Blood sample for PK for elanatamab		955.00	9.0	8595		0.00		0.00		0.00
Blood sample for ADA's and Nabs for elanatamab		955.00	5.0	4775		0.00		0.00		0.00
Blood Sample for sBCMA levels, MRD Tracking, Pfizer Prep D1 retained research samples		955.00	17.0	16235		0.00		0.00		0.00
Saliva sample for germline comparator		955.00	1.0	955		0.00		0.00		0.00
Study Coordinator - per hour	IRT Registration, Participant ID number, Eligibility criteria, Register with IRT, Randomization, Disease characteristics/treatment history, PROs, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapies, Subsequent anti-cancer therapies/date of progression, survival status, disease response assessment per	2,453.00	120.8	296322.4	3.20	7,849.60	3.70	9,076.10	3.20	7,849.60
Blood Sample for circulating proteins and metabolite analysis, TCR sequencing, and immune cell profiling		955.00	22.0	21010		0.00		0.00		0.00
Premedication administration and dispensing for CRS - oral acetaminophen		1,200.00	3.0	3600		0.00		0.00		0.00
Elanatamab administration (injection)		1,303.00	29.0	37787	1.00	1,303.00	1.00	1,303.00	1.00	1,303.00
Elanatamab dispensing (complex)		2,573.00	29.0	74617	1.00	2,573.00	1.00	2,573.00	1.00	2,573.00
CMV Testing	Local analysis	2,000.00	1.0	2000		0.00		0.00		0.00
	PSC Subtotal w/out Overhead			7,45,524.40		11,725.60		12,952.10		11,725.60
	PSC Subtotal with Overhead			8,94,629.28		14,070.72		15,542.52		14,070.72



DESCRIPTION OF COST	Comments	COST	Frequency of Procedure Total Number of times a procedure occurs based on PSC Structure	VISIT 32		VISIT 33		VISIT 34	
				Total PSC	f	EoT	f	F/U	f
Informed Consent and distribution of ECC		2,448.00	2.0	4896		0.00		0.00	0.00
Demography/medical history		4,000.00	1.0	4000		0.00		0.00	0.00
Physical exam	Includes vital signs, height/weight. Includes comprehensive physical exam at screening.	5,800.00	10.5	60900	1.00	5,800.00	1.00	5,800.00	0.00
Neurologic exam		5,400.00	16.0	86400	1.00	5,400.00	1.00	5,400.00	0.00
ICE Score (Encephalopathy assessment)		5,400.00	1.0	5400		0.00		0.00	0.00
Vital signs (temperature, HR, BP and O2 saturation)		1,045.00	19.0	19855		0.00		0.00	0.00
ECOG PS		1,045.00	1.0	1045		0.00		0.00	0.00
TriPLICATE 12-Lead ECG		1,500.00	5.0	7500	1.00	1,500.00		0.00	0.00
Single 12-Lead ECG		300.00	1.0	300		0.00		0.00	0.00
Lab handling and shipping of specimens, for central labs complex		966.00	12.0	11592	1.00	966.00		0.00	0.00
SPEP, SIFE, FLC	Blood draw for central lab	950.00	11.0	10450	1.00	950.00	1.00	950.00	1.00
UPEP, UFE	Urine collection for central lab	950.00	11.0	10450	1.00	950.00	1.00	950.00	1.00
Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	Blood draw for central lab	950.00	11.0	10450	1.00	950.00	1.00	950.00	1.00
Hematology	Local Lab	1,050.00	17.0	17850	1.00	1,050.00	1.00	1,050.00	0.00
Chemistry	Includes: BUN or Blood Urea, Creatinine, Glucose (non-fasting), Total Calcium, Sodium, Potassium, Chloride, AST, ALT, total bilirubin, Alkaline phosphatase, Albumin. Local lab. Magnesium, Phosphorous or Phosphates	2,060.00	10.0	20600	1.00	2,060.00	1.00	2,060.00	0.00
Beta-2 microglobulin	Local Lab	660.00	1.0	660		0.00		0.00	0.00
LDH	Local Lab	360.00	6.0	2160		0.00		0.00	0.00
Uric Acid	Local Lab	240.00	6.0	1440		0.00		0.00	0.00
TSH and reflex testing (T3 or free T3 and free T4)	Local Lab	770.00	4.0	3080	1.00	770.00		0.00	0.00
PT	Local Lab	300.00	1.0	300		0.00		0.00	0.00
INR	Local Lab	300.00	1.0	300		0.00		0.00	0.00
Blood sample for PK for elranatamab		955.00	9.0	8595	1.00	955.00		0.00	0.00
Blood sample for ADAs and Nabs for elranatamab		955.00	5.0	4775	1.00	955.00		0.00	0.00
Blood Sample for sBCMA levels, MRD Tracking, Pfizer Prep D1 retained research samples		955.00	17.0	16235	2.00	1,110.00		0.00	0.00
Saliva sample for germline comparator		955.00	1.0	955		0.00		0.00	0.00
Study Coordinator - per hour	IRT Registration, Participant ID number, Eligibility criteria, Register with IRT, Randomization, Disease characteristics/treatment history, PROs, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapies, Subsequent anti-cancer therapies/date of progression, survival status, disease response assessment per	2,453.00	120.8	296322.4	4.30	10,547.90	3.50	8,585.50	1.50
Blood Sample for circulating proteins and metabolite analysis, TCR sequencing, and immune cell profiling		955.00	22.0	21010	2.00	1,910.00		0.00	0.00
Premedication administration and dispensing for CRS - oral acetaminophen		1,200.00	3.0	3600		0.00		0.00	0.00
Elranatamab administration (injection)		1,303.00	29.0	37767		0.00		0.00	0.00
Elranatamab dispensing (complex)		2,573.00	29.0	74617		0.00		0.00	0.00
CMV Testing	Local analysis	2,000.00	1.0	2000		0.00		0.00	0.00
		PSC Subtotal w/out Overhead		7,45,524.40		36,673.90		25,745.50	6,529.50
		PSC Subtotal with Overhead		8,94,629.28		44,008.68		30,894.60	7,835.40



Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	Pre-Screening (Optional)	f	Screening
Additional Treatment Related Costs TO BE INVOICED	Serum Pregnancy test	WOCBP (on-site only)	1,000.00	13.0	13000		0.00	1.00
	Urine Pregnancy test	WOCBP (on-site only)	700.00	13.0	9100		0.00	1.00
	Premedication for etanercept - administration and dispensing (if oral)	Diphenhydramine and Dexamethasone	1,200.00	6.0	7200		0.00	0.00
	Premedication for etanercept - administration (if IV)	Diphenhydramine and Dexamethasone	4,997.00	6.0	29982		0.00	0.00
	Premedication for etanercept - dispensing (IV) (complex)	Diphenhydramine and Dexamethasone	2,573.00	6.0	15438		0.00	0.00
	Archival BMA sample for MRD (for cloneSEQ clonality (ID) Test)	Pre-screening	1,000.00	1.0	1000	1.00	1,000.00	0.00
	CMV testing	Local analysis	2,000.00	7.00	14000		0.00	0.00
Summary Costs	Per Subject Cost Subtotal			7,45,524.40		8,580.50		49,805.50
	Additional Cost Subtotal			89,720.00		1,000.00		1,700.00
	Subtotal			8,35,244.40		9,580.50		51,505.50
	Overhead			1,67,048.88		1,916.10		10,301.10
	INVESTIGATOR COST PER SUBJECT with Overhead			10,02,293.28		11,496.60		61,806.60
Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	C1D1	f	C1D4
Additional Treatment Related Costs TO BE INVOICED	Serum Pregnancy test	WOCBP (on-site only)	1,000.00	13.0	13000	1.00	1,000.00	0.00
	Urine Pregnancy test	WOCBP (on-site only)	700.00	13.0	9100	1.00	700.00	0.00
	Premedication for etanercept - administration and dispensing (if oral)	Diphenhydramine and Dexamethasone	1,200.00	6.0	7200	2.00	2,400.00	2.00
	Premedication for etanercept - administration (if IV)	Diphenhydramine and Dexamethasone	4,997.00	6.0	29982	2.00	9,994.00	2.00
	Premedication for etanercept - dispensing (IV) (complex)	Diphenhydramine and Dexamethasone	2,573.00	6.0	15438	2.00	5,146.00	2.00
	Archival BMA sample for MRD (for cloneSEQ clonality (ID) Test)	Pre-screening	1,000.00	1.0	1000		0.00	0.00
	CMV testing	Local analysis	2,000.00	7.00	14000	1.00	2,000.00	0.00
Summary Costs	Per Subject Cost Subtotal			7,45,524.40		50,796.90		29,506.60
	Additional Cost Subtotal			89,720.00		21,240.00		17,540.00
	Subtotal			8,35,244.40		72,039.90		47,346.60
	Overhead			1,67,048.88		14,407.98		9,469.32
	INVESTIGATOR COST PER SUBJECT with Overhead			10,02,293.28		86,447.88		56,815.92
Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	C1D15	f	C1D22
Additional Treatment Related Costs TO BE INVOICED	Serum Pregnancy test	WOCBP (on-site only)	1,000.00	13.0	13000	1.00	1,000.00	1.00
	Urine Pregnancy test	WOCBP (on-site only)	700.00	13.0	9100	1.00	700.00	1.00
	Premedication for etanercept - administration and dispensing (if oral)	Diphenhydramine and Dexamethasone	1,200.00	6.0	7200		0.00	0.00
	Premedication for etanercept - administration (if IV)	Diphenhydramine and Dexamethasone	4,997.00	6.0	29982		0.00	0.00
	Premedication for etanercept - dispensing (IV) (complex)	Diphenhydramine and Dexamethasone	2,573.00	6.0	15438		0.00	0.00
	Archival BMA sample for MRD (for cloneSEQ clonality (ID) Test)	Pre-screening	1,000.00	1.0	1000		0.00	0.00
	CMV testing	Local analysis	2,000.00	7.00	14000		0.00	0.00
Summary Costs	Per Subject Cost Subtotal			7,45,524.40		24,878.10		14,420.60
	Additional Cost Subtotal			89,720.00		1,700.00		3,760.00
	Subtotal			8,35,244.40		26,578.10		16,120.60
	Overhead			1,67,048.88		5,315.62		3,224.12
	INVESTIGATOR COST PER SUBJECT with Overhead			10,02,293.28		31,893.72		6,695.98
Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	C2D8	f	C2D15
Additional Treatment Related Costs TO BE INVOICED	Serum Pregnancy test	WOCBP (on-site only)	1,000.00	13.0	13000		0.00	0.00
	Urine Pregnancy test	WOCBP (on-site only)	700.00	13.0	9100		0.00	0.00
	Premedication for etanercept - administration and dispensing (if oral)	Diphenhydramine and Dexamethasone	1,200.00	6.0	7200		0.00	0.00
	Premedication for etanercept - administration (if IV)	Diphenhydramine and Dexamethasone	4,997.00	6.0	29982		0.00	0.00
	Premedication for etanercept - dispensing (IV) (complex)	Diphenhydramine and Dexamethasone	2,573.00	6.0	15438		0.00	0.00
	Archival BMA sample for MRD (for cloneSEQ clonality (ID) Test)	Pre-screening	1,000.00	1.0	1000		0.00	0.00
	CMV testing	Local analysis	2,000.00	7.00	14000		0.00	0.00
Summary Costs	Per Subject Cost Subtotal			7,45,524.40		12,775.60		18,175.60
	Additional Cost Subtotal			89,720.00		0.00		0.00
	Subtotal			8,35,244.40		12,775.60		18,175.60
	Overhead			1,67,048.88		2,555.12		2,555.12
	INVESTIGATOR COST PER SUBJECT with Overhead			10,02,293.28		15,330.72		15,330.72



Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	C3D1	f	C3D4	f	C3D8
TO BE INVOICED	Serum Pregnancy test	WOCBP (on-site only)	1,000.00	13.0	13000	1.00	1,000.00	0.00	0.00	0.00
	Urine Pregnancy test	WOCBP (on-site only)	700.00	13.0	9100	1.00	700.00	0.00	0.00	0.00
	Premedication for eranatrab - administration and dispensing (if oral)	Diphenhydramine and Dexamehasone	1,200.00	6.0	7200	0.00	0.00	0.00	0.00	0.00
	Premedication for eranatrab - administration (if IV)	Diphenhydramine and Dexamehasone	4,997.00	6.0	29982	0.00	0.00	0.00	0.00	0.00
	Premedication for eranatrab - dispensing (IV) (complex)	Diphenhydramine and Dexamehasone	2,573.00	6.0	15438	0.00	0.00	0.00	0.00	0.00
	Archival BMA sample for MRD (for clonoSEQ clonality (ID) Test)	Pre-screening	1,000.00	1.0	1000	0.00	0.00	0.00	0.00	0.00
Summary Costs	CMV testing	Local analysis	2,000.00	7.00	14000	1.00	2,000.00	0.00	0.00	0.00
	Per Subject Cost Subtotal			7,45,524.40		36,359.90	0.00	0.00	11,725.60	
	Additional Cost Subtotal			89,720.00		3,700.00	0.00	0.00	0.00	
	Subtotal			8,35,244.40		40,059.90	0.00	0.00	11,725.60	
	Overhead			1,67,048.88		8,013.98	0.00	0.00	2,345.12	
INVESTIGATOR COST PER SUBJECT with Overhead					10,02,293.28	45,791.88	0.00	0.00	14,070.72	

Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	C3D15	f	C3D22	f	C4D1
TO BE INVOICED	Serum Pregnancy test	WOCBP (on-site only)	1,000.00	13.0	13000	0.00	0.00	1,000.00	0.00	1,000.00
	Urine Pregnancy test	WOCBP (on-site only)	700.00	13.0	9100	0.00	0.00	1,000.00	0.00	700.00
	Premedication for eranatrab - administration and dispensing (if oral)	Diphenhydramine and Dexamehasone	1,200.00	6.0	7200	0.00	0.00	0.00	0.00	0.00
	Premedication for eranatrab - administration (if IV)	Diphenhydramine and Dexamehasone	4,997.00	6.0	29982	0.00	0.00	0.00	0.00	0.00
	Premedication for eranatrab - dispensing (IV) (complex)	Diphenhydramine and Dexamehasone	2,573.00	6.0	15438	0.00	0.00	0.00	0.00	0.00
	Archival BMA sample for MRD (for clonoSEQ clonality (ID) Test)	Pre-screening	1,000.00	1.0	1000	0.00	0.00	0.00	0.00	0.00
Summary Costs	CMV testing	Local analysis	2,000.00	7.00	14000	0.00	0.00	1,000.00	2,000.00	
	Per Subject Cost Subtotal			7,45,524.40		19,402.10	0.00	11,725.60	39,594.90	
	Additional Cost Subtotal			89,720.00		0.00	0.00	0.00	3,700.00	
	Subtotal			8,35,244.40		19,402.10	0.00	11,725.60	43,294.90	
	Overhead			1,67,048.88		3,680.42	0.00	2,345.12	8,658.98	
INVESTIGATOR COST PER SUBJECT with Overhead					10,02,293.28	23,282.52	0.00	0.00	14,070.72	51,953.88

Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	C4D8	f	C4D15	f	C4D22
TO BE INVOICED	Serum Pregnancy test	WOCBP (on-site only)	1,000.00	13.0	13000	0.00	0.00	0.00	0.00	0.00
	Urine Pregnancy test	WOCBP (on-site only)	700.00	13.0	9100	0.00	0.00	0.00	0.00	0.00
	Premedication for eranatrab - administration and dispensing (if oral)	Diphenhydramine and Dexamehasone	1,200.00	6.0	7200	0.00	0.00	0.00	0.00	0.00
	Premedication for eranatrab - administration (if IV)	Diphenhydramine and Dexamehasone	4,997.00	6.0	29982	0.00	0.00	0.00	0.00	0.00
	Premedication for eranatrab - dispensing (IV) (complex)	Diphenhydramine and Dexamehasone	2,573.00	6.0	15438	0.00	0.00	0.00	0.00	0.00
	Archival BMA sample for MRD (for clonoSEQ clonality (ID) Test)	Pre-screening	1,000.00	1.0	1000	0.00	0.00	0.00	0.00	0.00
Summary Costs	CMV testing	Local analysis	2,000.00	7.00	14000	0.00	0.00	0.00	0.00	0.00
	Per Subject Cost Subtotal			7,45,524.40		11,725.60	0.00	18,352.10	0.00	11,725.60
	Additional Cost Subtotal			89,720.00		0.00	0.00	0.00	0.00	
	Subtotal			8,35,244.40		11,725.60	0.00	18,352.10	0.00	11,725.60
	Overhead			1,67,048.88		2,345.12	0.00	3,670.42	0.00	2,345.12
INVESTIGATOR COST PER SUBJECT with Overhead					10,02,293.28	22,022.52	0.00	0.00	14,070.72	

Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	C5D1	f	C5D4	f	C5D8	f	C5D15
TO BE INVOICED	Serum Pregnancy test	WOCBP (on-site only)	1,000.00	13.0	13000	1.00	1,000.00	0.00	0.00	0.00	0.00	0.00
	Urine Pregnancy test	WOCBP (on-site only)	700.00	13.0	9100	1.00	700.00	0.00	0.00	0.00	0.00	0.00
	Premedication for eranatrab - administration and dispensing (if oral)	Diphenhydramine and Dexamehasone	1,200.00	6.0	7200	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Premedication for eranatrab - administration (if IV)	Diphenhydramine and Dexamehasone	4,997.00	6.0	29982	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Premedication for eranatrab - dispensing (IV) (complex)	Diphenhydramine and Dexamehasone	2,573.00	6.0	15438	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Archival BMA sample for MRD (for clonoSEQ clonality (ID) Test)	Pre-screening	1,000.00	1.0	1000	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Summary Costs	CMV testing	Local analysis	2,000.00	7.00	14000	1.00	2,000.00	0.00	0.00	0.00	0.00	0.00
	Per Subject Cost Subtotal			7,45,524.40		34,459.90	0.00	11,725.60	0.00	18,352.10		
	Additional Cost Subtotal			89,720.00		3,700.00	0.00	0.00	0.00	0.00		
	Subtotal			8,35,244.40		38,159.90	0.00	11,725.60	0.00	18,352.10		
	Overhead			1,67,048.88		7,631.98	0.00	2,345.12	0.00	3,670.42		
INVESTIGATOR COST PER SUBJECT with Overhead					10,02,293.28	45,791.88	0.00	0.00	14,070.72	22,022.52		



	Additional Procedures that may not apply to all Patients	COST	Total Number of times a procedure may occur	Total Potential PSC	f	C5D22	f	C6D1	f	C6D8
TO BE INVOICED	Serum Pregnancy test	WOCBP (on-site only)	1,000.00	13.0	13000	0.00	1.00	1,000.00	0.00	
	Urine Pregnancy test	WOCBP (on-site only)	700.00	13.0	9100	0.00	1.00	700.00	0.00	
	Premedication for etanercept - administration and dispensing (if oral)	Diphenhydramine and Dexmethasone	1,200.00	6.0	7200	0.00	0.00	0.00	0.00	
	Premedication for etanercept - administration (if IV)	Diphenhydramine and Dexmethasone	4,997.00	6.0	29982	0.00	0.00	0.00	0.00	
	Premedication for etanercept - dispensing (IV) (complex)	Diphenhydramine and Dexmethasone	2,573.00	6.0	15438	0.00	0.00	0.00	0.00	
	Archival BMA sample for MRD (for cloneSEQ clonality (ID) Test)	Pre-screening	1,000.00	1.0	1000	0.00	0.00	0.00	0.00	
	CMV testing	Local analysis	2,000.00	7.00	14000	0.00	1.00	2,000.00	0.00	
Summary Costs	Per Subject Cost Subtotal			7,45,524.40		11,725.60		34,459.90		11,725.60
	Additional Cost Subtotal			89,720.00		0.00		3,700.00		0.00
	Subtotal			8,35,244.40		11,725.60		38,159.90		11,725.60
	Overhead			1,67,048.88		2,345.12		7,831.98		2,345.12
INVESTIGATOR COST PER SUBJECT with Overhead					10,02,293.28	14,070.72		45,791.88		14,070.72

	Additional Procedures that may not apply to all Patients	COST	Total Number of times a procedure may occur	Total Potential PSC	f	C6D15	f	C6D22	f	C7D1
TO BE INVOICED	Serum Pregnancy test	WOCBP (on-site only)	1,000.00	13.0	13000	0.00	0.00	1.00	1,000.00	
	Urine Pregnancy test	WOCBP (on-site only)	700.00	13.0	9100	0.00	0.00	1.00	700.00	
	Premedication for etanercept - administration and dispensing (if oral)	Diphenhydramine and Dexmethasone	1,200.00	6.0	7200	0.00	0.00	0.00	0.00	
	Premedication for etanercept - administration (if IV)	Diphenhydramine and Dexmethasone	4,997.00	6.0	29982	0.00	0.00	0.00	0.00	
	Premedication for etanercept - dispensing (IV) (complex)	Diphenhydramine and Dexmethasone	2,573.00	6.0	15438	0.00	0.00	0.00	0.00	
	Archival BMA sample for MRD (for cloneSEQ clonality (ID) Test)	Pre-screening	1,000.00	1.0	1000	0.00	0.00	0.00	0.00	
	CMV testing	Local analysis	2,000.00	7.00	14000	0.00	0.00	1.00	2,000.00	
Summary Costs	Per Subject Cost Subtotal			7,45,524.40		18,352.10		11,725.60		38,094.00
	Additional Cost Subtotal			89,720.00		0.00		3,700.00		
	Subtotal			8,35,244.40		18,352.10		11,725.60		41,794.90
	Overhead			1,67,048.88		3,070.42		2,345.12		8,358.98
INVESTIGATOR COST PER SUBJECT with Overhead					10,02,293.28	22,022.52		14,070.72		50,153.88

	Additional Procedures that may not apply to all Patients	COST	Total Number of times a procedure may occur	Total Potential PSC	f	C7D8	f	C7D15	f	C7D22
TO BE INVOICED	Serum Pregnancy test	WOCBP (on-site only)	1,000.00	13.0	13000	0.00	0.00	0.00	0.00	
	Urine Pregnancy test	WOCBP (on-site only)	700.00	13.0	9100	0.00	0.00	0.00	0.00	
	Premedication for etanercept - administration and dispensing (if oral)	Diphenhydramine and Dexmethasone	1,200.00	6.0	7200	0.00	0.00	0.00	0.00	
	Premedication for etanercept - administration (if IV)	Diphenhydramine and Dexmethasone	4,997.00	6.0	29982	0.00	0.00	0.00	0.00	
	Premedication for etanercept - dispensing (IV) (complex)	Diphenhydramine and Dexmethasone	2,573.00	6.0	15438	0.00	0.00	0.00	0.00	
	Archival BMA sample for MRD (for cloneSEQ clonality (ID) Test)	Pre-screening	1,000.00	1.0	1000	0.00	0.00	0.00	0.00	
	CMV testing	Local analysis	2,000.00	7.00	14000	0.00	0.00	0.00	0.00	
Summary Costs	Per Subject Cost Subtotal			7,45,524.40		11,725.60		12,952.10		11,725.60
	Additional Cost Subtotal			89,720.00		0.00		0.00		0.00
	Subtotal			8,35,244.40		11,725.60		12,952.10		11,725.60
	Overhead			1,67,048.88		2,345.12		2,590.42		2,345.12
INVESTIGATOR COST PER SUBJECT with Overhead					10,02,293.28	14,070.72		15,542.52		14,070.72

	Additional Procedures that may not apply to all Patients	COST	Total Number of times a procedure may occur	Total Potential PSC	f	EoT	f	FU	f	Long Term F/U Visit
TO BE INVOICED	Serum Pregnancy test	WOCBP (on-site only)	1,000.00	13.0	13000	1.00	1,000.00	1.00	1,000.00	0.00
	Urine Pregnancy test	WOCBP (on-site only)	700.00	13.0	9100	1.00	700.00	1.00	700.00	0.00
	Premedication for etanercept - administration and dispensing (if oral)	Diphenhydramine and Dexmethasone	1,200.00	6.0	7200	0.00	0.00	0.00	0.00	
	Premedication for etanercept - administration (if IV)	Diphenhydramine and Dexmethasone	4,997.00	6.0	29982	0.00	0.00	0.00	0.00	
	Premedication for etanercept - dispensing (IV) (complex)	Diphenhydramine and Dexmethasone	2,573.00	6.0	15438	0.00	0.00	0.00	0.00	
	Archival BMA sample for MRD (for cloneSEQ clonality (ID) Test)	Pre-screening	1,000.00	1.0	1000	0.00	0.00	0.00	0.00	
	CMV testing	Local analysis	2,000.00	7.00	14000	0.00	0.00	0.00	0.00	
Summary Costs	Per Subject Cost Subtotal			7,45,524.40		38,673.90		25,745.50		6,529.50
	Additional Cost Subtotal			89,720.00		1,700.00		1,700.00		0.00
	Subtotal			8,35,244.40		38,373.90		27,445.50		6,529.50
	Overhead			1,67,048.88		7,674.78		5,489.10		1,305.90
INVESTIGATOR COST PER SUBJECT with Overhead					10,02,293.28	46,048.68		32,934.60		7,835.40



Additional Procedures Not included in the Per Subject Cost (Procedures not tied to a specific visit) - All Fees Inclusive of Overhead			
---	--	--	--

Other Study Level Costs	Procedure	Comments	Cost
	Pharmacy start-up fee	Payable at start-up, one-time flat	49,810.00
	Radiology Set-up Fee	Payable at start-up, one-time flat	28,507.00
	Admin start-up fee	Payable at start-up, one-time flat	60,000.00
	Record Archiving	To be invoiced, one-time at close out	50,000.00
	SAE reporting	To be invoiced as incurred	6,835.00
	Pharmacy close out	To be invoiced, one-time at close out	20,452.00
Screen Fails	Applicable to subjects who SF at Visit 1. Cost reflects V1 with 25% reduction, no overhead paid. Max 5 SFs per site.		37,354.13

Additional Procedures Not included in the Per Subject Cost (Procedures not tied to a specific visit) - All Fees Inclusive of Overhead			
---	--	--	--

Other Study Level Costs	Procedure	Comments	Cost
	Subject travel reimbursement	To be invoiced as incurred, flat fee per visit	2,000.00
	ECHO	To be invoiced as incurred, includes interpretation and	35,374.38
	MUGA	To be invoiced as incurred, includes interpretation and	35,242.80
	PET/CT Chest	To be invoiced as incurred, includes interpretation and	1,12,436.40
	PET/CT Abdomen	To be invoiced as incurred, includes interpretation and report	1,12,436.40
	PET/CT Pelvis	To be invoiced as incurred, includes interpretation and report	1,12,436.40
	CT Chest	To be invoiced as incurred, includes interpretation and	39,231.48
	CT Abdomen	To be invoiced as incurred, includes interpretation and report	49,734.66



Additional Procedures Not included in the Per Subject Cost (Procedures not tied to a specific visit) - All Fees Inclusive of Overhead

Other Study Level Costs	Procedure	Comments	Cost
	CT Pelvis	To be invoiced as incurred, includes interpretation and report	34,235.31
	MRI Chest	To be invoiced as incurred, includes interpretation and report	1,25,256.42
	MRI Abdomen	To be invoiced as incurred, includes interpretation and report	76,711.14
	MRI Pelvis	To be invoiced as incurred, includes interpretation and report	88,656.54
	PET/CT Scan Whole Body	To be invoiced as incurred, includes interpretation and report	1,39,998.54
	CT Brain	To be invoiced as incurred, includes interpretation and report	34,360.44
	MRI Brain	To be invoiced as incurred, includes interpretation and report	77,552.22

Additional Procedures Not included in the Per Subject Cost (Procedures not tied to a specific visit) - All Fees Inclusive of Overhead

Other Study Level Costs	Procedure	Comments	Cost
	CT Neck	To be invoiced as incurred, includes interpretation and report	34,610.70
	MRJ Neck	To be invoiced as incurred, includes interpretation and report	87,293.01
	Participant Hospitalization - per day - Arm A & Arm C only	To be invoiced as required per Protocol	21,269.00
	Bone Marrow Aspirate - Fresh	To be invoiced as required per Protocol	16,331.40
	Bone Marrow Biopsy	To be invoiced as required per Protocol	12,920.64
	Handling/Shipping of BMA/BMB Samples (Complex)	To be invoiced as incurred	1,159.20
	FISH analysis / Caryotyping	To be invoiced as required per Protocol.	7,729.68
	FISH / Caryotyping - report	To be invoiced as required per Protocol	5,278.68
	Pre-screening /chart review	Per chart. To be invoiced up to 25 charts. Additional to be invoiced with prior approval from Pfizer.	2,943.60



Additional Procedures Not included in the Per Subject Cost (Procedures not tied to a specific visit) - All Fees Inclusive of Overhead			
Other Study Level Costs	Procedure	Comments	Cost
	Acetaminophen or paracetamol	To be invoiced as incurred, per bottle (25 count). Receipts/documentation required with invoice	185.00
	Diphenhydramine	To be invoiced as incurred, per bottle (25 count). Receipts/documentation required with invoice	185.00
	Dexamethasone	To be invoiced as incurred, per bottle (25 count). Receipts/documentation required with invoice	185.00
	Dermatologist Consultation	To be invoiced if required per Protocol. Per consultation	7,292.37
	Neurologist Consultation	To be invoiced if required per Protocol. Per consultation	6,305.52
	Beta-2 microglobulin	To be invoiced, if additional required per Protocol	792.00
	LDH	To be invoiced, if additional required per Protocol	432.00
	Uric Acid	To be invoiced, if additional required per Protocol	288.00
	Blood or Urine Sample for Central Lab analysis	If additional blood or urine samples required, per Protocol - to be invoiced per sample	1,140.00



Additional Procedures Not included in the Per Subject Cost (Procedures not tied to a specific visit) - All Fees Inclusive of Overhead			
Other Study Level Costs	Procedure	Comments	Cost
	Shipping, handling for central lab (Complex)	If additional central lab shipping required, per Protocol, if additional instances required - per central lab shipment	1,159.20
	Day 1: Additional Cycles (starting with C8)	Paid based on EDC data (not invoiceable). Any invoiceables from the Additional Treatment Related Costs section for Cycle 7 costs above may be invoiced additionally as incurred for the cycle (not included in amount listed here).	45,713.88
	Day 8: Additional Cycles (starting with C8)	Paid based on EDC data (not invoiceable). Any invoiceables from the Additional Treatment Related Costs section for Cycle 7 costs above may be invoiced additionally as incurred for the cycle (not included in amount listed here).	14,070.72
	Day 15: Additional Cycles (starting with C8)	Paid based on EDC data (not invoiceable). Any invoiceables from the Additional Treatment Related Costs section for Cycle 7 costs above may be invoiced additionally as incurred for the cycle (not included in amount listed here).	15,542.52
	Day 22: Additional Cycles (starting with C8)	Paid based on EDC data (not invoiceable). Any invoiceables from the Additional Treatment Related Costs section for Cycle 7 costs above may be invoiced additionally as incurred for the cycle (not included in amount listed here).	14,070.72



Additional Procedures Not included in the Per Subject Cost (Procedures not tied to a specific visit) - All Fees Inclusive of Overhead

Other Study Level Costs	Procedure	Comments	Cost
	Additional 12-Lead ECG (Triplicate)	To be invoiced, if additional required per Protocol	1,800.00
	Additional 12-Lead ECG (Singlet)	To be invoiced, if additional required per Protocol	360.00
	Cardiologist Consultation	To be invoiced if required per Protocol. Per consultation	6,127.50
	Hematology	If additional labs required per Protocol. To be invoiced as incurred	1,260.00
	Chemistry	If additional labs required per Protocol. To be invoiced as incurred	2,472.00
	PT	If additional labs required per Protocol. To be invoiced as incurred	360.00
	INR	If additional labs required per Protocol. To be invoiced as incurred	360.00
	TSH and reflex testing (T3 and free T4)	If additional labs required per Protocol. To be invoiced as incurred	924.00
	Additional LTFU Visits	Paid based on EDC data, per additional LTFU visit	7,835.40
	Bronchodilator or Inhaled Corticosteroid	To be invoiced, if required per Protocol, per inhaler. Receipts/documentation required with invoice	1,107.00
	Reconsenting	To be invoiced as incurred	1,468.80



Additional Procedures Not included in the Per Subject Cost (Procedures not tied to a specific visit) - All Fees Inclusive of Overhead			
Other Study Level Costs	Procedure	Comments	Cost
	BMA - archived alternative sample (non-fresh)	To be invoiced per Protocol.	1,200.00
	Pre-Screening Screen Failures	To be invoiced up to total of pre-screening visit. Cap of 5 per site (additional eligible for invoice with prior Pfizer approval)	10,296.60
	HBsAg	To be invoiced as incurred	1,260.33
	HBcAb	To be invoiced as incurred	4,940.70
	HBsAb	To be invoiced as incurred	3,226.29
	HBV DNA viral load	To be invoiced as incurred	9,914.94
	HCV Testing	To be invoiced as incurred	5,448.00
	Paxlovid - dispensing & administration instruction	To be invoiced as incurred.	1,440.00
	COVID-19 Testing - PCR	To be invoiced if required per Protocol.	1,842.00
	COVID-19 Testing - Rapid Antigen Kits	To be invoiced based on actuals up to amount listed per kit.	1,000.00
	Plasma Cells % - local analysis	To be invoiced as incurred.	1,071.99
	Kappa Light Chain - local analysis	To be invoiced as incurred.	2,759.31
	Lambda Light Chain - local analysis	To be invoiced as incurred.	2,759.31



ARM B

COMPOUND:	REGN03135	AMENDMENT:	PA2	INVESTIGATOR:	Dr. Sanjiv Verma
STUDY NUMBER:	C1071007	ARM/CHART:	Arm B	INSTITUTION:	Saint Remy
TITLE:	REGN03135 / A RANDOMIZED, 2-ARM PHASE 3 STUDY OF ELRANATINAB (REGN03135) VERSUS LENALIDOMIDE IN PATIENTS WITH NEWLY DIAGNOSED MULTIPLE MYELOMA AFTER UNDERGOING ALLOGENIC STEM-CELL TRANSPLANTATION			CODE:	NA
COUNTRY/DOCTOR:	India - IND	OVERHEAD:	23.00%		

Per Subject Cost

DESCRIPTION OF COST	Comments	COST	Frequency of Procedure	VISIT 1		VISIT 2	
				Total PSC	f	Pre-Screening (Optional)	f
Informed Consent and distribution of ECC		2,448.00	2.0	4896	1.00	2,448.00	1.00
Demography/medical history		4,000.00	1.0	4000	0.00	1.00	4,000.00
Physical exam	Includes vital signs, height/weight. Includes comprehensive physical exam at screening.	5,800.00	13.5	78300	0.00	1.50	8,700.00
Neurologic exam		5,400.00	16.0	86400	0.00	1.00	5,400.00
ICIE Score (Encephalopathy assessment)		5,400.00	1.0	5400	0.00		0.00
ECOG PS		1,045.00	1.0	1045	0.00	1.00	1,045.00
Tripleate 12-Lead ECG		1,500.00	5.0	7500	0.00		0.00
Single 12-Lead ECG		300.00	1.0	300	0.00	1.00	300.00
Lab handling and shipping of specimens, complex	for central labs	966.00	11.0	10626	0.00	1.00	966.00
SPEP, SIFE, FLC	Blood draw for central lab	950.00	11.0	10450	0.00	1.00	950.00
UPEP, UIFE	Urine collection for central lab	950.00	11.0	10450	0.00	1.00	950.00
Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	Blood draw for central lab	950.00	11.0	10450	0.00	1.00	950.00
Hematology	Local Lab	1,050.00	17.0	17850	0.00	1.00	1,050.00
Chemistry	Includes: Blood or BUN Urea, Creatinine, Glucose (non-fasting), Total Calcium, Sodium, Potassium, Chloride, AST, ALT, total bilirubin, Alkaline phosphatase, Albumin, Local lab, Magnesium, Phosphorous or Phosphates	2,060.00	10.0	20500	0.00	1.00	2,060.00
Beta-2 microglobulin	Local Lab	660.00	1.0	660	0.00	1.00	660.00
LDH	Local Lab	350.00	5.0	1800	0.00	1.00	360.00
Uric Acid	Local Lab	240.00	5.0	1200	0.00	1.00	240.00
TSH and reflex testing (T3 or free T3 and free T4)	Local Lab	770.00	4.0	3080	0.00	1.00	770.00
PT	Local Lab	300.00	1.0	300	0.00	1.00	300.00
INR	Local Lab	300.00	1.0	300	0.00	1.00	300.00
Blood Sample for sBCMA levels, MRD Tracking, Pfizer Prep D1 retained research samples		950.00	17.0	16150	0.00	2.00	1,900.00
Saliva sample for germline comparator		950.00	1.0	950	0.00		0.00
Study Coordinator - per hour	IRT Registration, Participant ID number, Eligibility criteria, Register with IRT, Randomization, Disease characteristics/treatment history, PROs, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapies, Subsequent anti-cancer therapies/date of progression, survival status, disease response assessment per IMWG criteria, Contraception check, remote / on-site monitoring support, facilities and scheduling	2,453.00	81.9	200900.7	2.50	6,132.50	5.50
							13,491.50
Blood Sample for circulating proteins and metabolic analysis, TCR sequencing, and immune cell profiling	Arm B	955.00	18.0	17190	0.00	1.00	955.00
Lenalidomide administration/dispensing	Arm B	1,097.00	17.0	15649	0.00		0.00
CMV Testing	Local analysis	2,000.00	1.0	2000	0.00	1.00	2,000.00
				5,31,446.70		6,580.50	49,795.50
				PSC Subtotal with Overhead			
						6,37,736.04	10,296.60
							59,754.60



DESCRIPTION OF COST	Comments	Frequency of Procedure	Total PSC	VISIT 3		VISIT 4		VISIT 5	
				COST	Total Number of times a procedure occurs based on PSC Structure	f	C1D1	f	C1D15
Informed Consent and distribution of ECC		2,443.00	2.0	4886		0.00	0.00	0.00	0.00
Demography/medical history		4,000.00	1.0	4000		0.00	0.00	0.00	0.00
Physical exam:	Includes vital signs, height/weight. Includes comprehensive physical exam at screening.	5,800.00	13.5	78300	1.00	5,800.00	1.00	5,800.00	1.00
Neurologic exam		5,400.00	16.0	86400	1.00	5,400.00	0.00	1.00	5,400.00
ICSE Score (Encephalopathy assessment)		5,400.00	1.0	5400	1.00	5,400.00	0.00	0.00	0.00
ECOG PS		1,045.00	1.0	1045		0.00	0.00	0.00	0.00
Triphasic 12-Lead ECG		1,500.00	5.0	7500	1.00	1,500.00	1.00	1,500.00	0.00
Single 12-Lead ECG		300.00	1.0	300		0.00	0.00	0.00	0.00
Lab handling and shipping of specimens, complex	for central labs	966.00	11.0	10628	1.00	966.00	1.00	966.00	1.00
SPER, SIFE, FLC	Blood draw for central lab	950.00	11.0	10450	1.00	950.00	0.00	0.00	0.00
URER, UFE	Urine collection for central lab	950.00	11.0	10450	1.00	950.00	0.00	0.00	0.00
Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	Blood draw for central lab	950.00	11.0	10450	1.00	950.00	0.00	0.00	0.00
Hematology	Local Lab	1,050.00	17.0	17850	1.00	1,050.00	1.00	1,050.00	1.00
Chemistry	Includes: Blood or BUN Urea, Creatinine, Glucose (non-fasting), Total Calcium, Sodium, Potassium, Chloride, AST, ALT, total bilirubin, Alkaline phosphatase, Albumin. Local lab, Magnesium, Phosphorous or Phosphates	2,060.00	10.0	20600	1.00	2,060.00	0.00	0.00	0.00
Beta-2 microglobulin	Local Lab	660.00	1.0	660		0.00	0.00	0.00	0.00
LDH	Local Lab	360.00	5.0	1800	1.00	360.00	1.00	360.00	1.00
Uric Acid	Local Lab	240.00	5.0	1200	1.00	240.00	1.00	240.00	1.00
TSH and reflex testing (T3 or free T3 and free T4)	Local Lab	770.00	4.0	3080		0.00	0.00	0.00	0.00
PT	Local Lab	300.00	1.0	300		0.00	0.00	0.00	0.00
INR	Local Lab	300.00	1.0	300		0.00	0.00	0.00	0.00
Blood Sample for sBCMA levels, MRD Tracking, Pfizer Prep D1 retained research samples		950.00	17.0	16150	3.00	2,850.00	1.00	950.00	0.00
Saliva sample for germline comparator		950.00	1.0	950	1.00	950.00		0.00	0.00
Study Coordinator - per hour	IRT Registration, Participant ID number, Eligibility criteria, Register with IRT, Randomization, Disease characteristics/ treatment history, PROs, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapies, Subsequent anti-cancer therapies/date of progression, survival status, disease response assessment per IMWG criteria, Contraception check, remote / on-site monitoring support, facilities and scheduling	2,453.00	81.9	200900.7	4.30	10,547.90	3.20	7,849.60	3.70
Blood Sample for circulating proteins and metabolic analysis, TCR sequencing, and immune cell profiling	Arm B	955.00	18.0	17190	3.00	2,865.00		0.00	3.00
Lenalidomide administration/dispensing	Arm B	1,097.00	17.0	18649	1.00	1,097.00	1.00	1,097.00	1.00
CMV Testing	Local analysis	2,000.00	1.0	2000		0.00	0.00	0.00	0.00
			PSC Subtotal without Overhead		5,31,446.70		43,835.90		19,812.60
			PSC Subtotal with Overhead			6,37,736.04		52,723.08	
							23,775.12		32,224.92



DESCRIPTION OF COST	Comments	COST	Frequency of Procedure	Total PSC	VISIT 6		VISIT 7		VISIT 8	
					f	C1D22	f	C2D1	f	C2D8
Informed Consent and distribution of ECC		2,448.00	2.0	4896		0.00	0.00	0.00	0.00	0.00
Demography/medical history		4,000.00	1.0	4000		0.00	0.00	0.00	0.00	0.00
Physical exam	Includes vital signs, height/weight. Includes comprehensive physical exam at screening.	5,600.00	13.5	78300	1.00	5,600.00	1.00	5,600.00	0.00	0.00
Neurologic exam		5,400.00	16.0	86400		0.00	1.00	5,400.00	0.00	0.00
ICE Score (Encephalopathy assessment)		5,400.00	1.0	5400		0.00	0.00	0.00	0.00	0.00
ECOG PS		1,045.00	1.0	1045		0.00	0.00	0.00	0.00	0.00
Tricarboxy 12-Lead ECG		1,500.00	5.0	7500		0.00	1.00	1,500.00	0.00	0.00
Single 12-Lead ECG		300.00	1.0	300		0.00	0.00	0.00	0.00	0.00
Lab handling and shipping of specimens, for central labs, complex		966.00	11.0	10626		0.00	1.00	666.00	0.00	0.00
SRER, SIFE, FLC	Blood draw for central lab	950.00	11.0	10450		0.00	1.00	950.00	0.00	0.00
UPER, UFE	Urine collection for central lab	950.00	11.0	10450		0.00	1.00	950.00	0.00	0.00
Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	Blood draw for central lab	950.00	11.0	10450		0.00	1.00	950.00	0.00	0.00
Hematology										
Chemistry	Local Lab Includes: Blood or BUN Urea, Creatinine, Glucose (non-fasting), Total Calcium, Sodium, Potassium, Chloride, AST, ALT, total bilirubin, Alkaline phosphatase, Albumin. Local lab, Magnesium, Phosphorous or Phosphates	1,050.00	17.0	17850	1.00	1,050.00	1.00	1,050.00	1.00	1,050.00
		2,060.00	10.0	20600		0.00	1.00	2,060.00		
Beta-2 microglobulin	Local Lab	660.00	1.0	660		0.00	0.00	0.00	0.00	0.00
LDH	Local Lab	360.00	5.0	1800	1.00	360.00	0.00	0.00	0.00	0.00
Uric Acid	Local Lab	240.00	5.0	1200	1.00	240.00	0.00	0.00	0.00	0.00
TSH and reflex testing (T3 or free T3 and free T4)	Local Lab	770.00	4.0	3080		0.00	0.00	0.00	0.00	0.00
PT	Local Lab	300.00	1.0	300		0.00	0.00	0.00	0.00	0.00
INR	Local Lab	300.00	1.0	300		0.00	0.00	0.00	0.00	0.00
Blood Sample for sBCMA levels, NRD Tracking, Pfizer Prep D1 retained research samples		950.00	17.0	16150		0.00	2.00	1,600.00		0.00
Saliva sample for germline comparator		950.00	1.0	950		0.00	0.00	0.00	0.00	0.00
Study Coordinator - per hour	IRT Registration, Participant ID number, Eligibility criteria, Register with IRT, Randomization, Disease characteristics/treatment history, PROs, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapies, Subsequent anti-cancer therapies/date of progression, survival status, disease response assessment per IMWG criteria, Contraception check, remote / on-site monitoring support, facilities and scheduling	2,453.00	81.9	200900.7	3.20	7,849.60	4.33	10,547.90	3.20	7,849.60
Blood Sample for circulating proteins and metabolic analysis, TCR sequencing, and immune cell profiling	Arm B	955.00	18.0	17190		0.00	2.00	1,910.00		0.00
Lenalidomide administration/dispensing	Arm B	1,097.00	17.0	18649	1.00	1,097.00	1.00	1,097.00	1.00	1,097.00
CMV Testing	Local analysis	2,000.00	1.0	2000		0.00	0.00	0.00	0.00	0.00
	PSC Subtotal w/out Overhead			53,1446.70		16,396.60		35,080.90		9,996.60
	PSC Subtotal with Overhead			63,7736.04		19,675.92		42,097.08		11,995.92



DESCRIPTION OF COST	Comments	Frequency of Procedure	VISIT 9		VISIT 10		VISIT 11				
			COST	Total Number of times a procedure occurs based on PSC Structure	Total PSC	f	C2D15	f	C2D22	f	C3D1
Informed Consent and distribution of ECC		2,448.00	2.0	4896	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Demography/medical history		4,000.00	1.0	4000	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Physical exam	Includes vital signs, height/weight. Includes comprehensive physical exam at screening	5,500.00	13.5	78300	0.00	0.00	1.00	5,600.00			
Neurologic exam		5,400.00	16.0	86400	1.00	5,400.00	0.00	1.00	5,400.00		
ICE Score (Encephalopathy assessment)		5,400.00	1.0	5400	0.00	0.00	0.00	0.00	0.00		
ECOG PS		1,045.00	1.0	1045	0.00	0.00	0.00	0.00	0.00		
Triphasic 12-Lead ECG		1,500.00	5.0	7500	0.00	0.00	0.00	0.00	0.00		
Single 12-Lead ECG		300.00	1.0	300	0.00	0.00	0.00	0.00	0.00		
Lab handling and shipping of specimens, for central labs, complex		866.00	11.0	10626	0.00	0.00	1.00	966.00			
SPEP, SIFE, FLC	Blood draw for central lab	950.00	11.0	10450	0.00	0.00	1.00	950.00			
UPEP, UFE	Urine collection for central lab	950.00	11.0	10450	0.00	0.00	1.00	950.00			
Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	Blood draw for central lab	950.00	11.0	10450	0.00	0.00	1.00	950.00			
Hematology	Local Lab	1,050.00	17.0	17850	1.00	1,050.00	1.00	1,050.00	1.00	1,050.00	
Chemistry	Includes: Blood or BUN Urea, Creatinine, Glucose (non-fasting), Total Calcium, Sodium, Potassium, Chloride, AST, ALT, total bilirubin, Alkaline phosphatase, Albumin. Local lab, Magnesium, Phosphorous or Phosphates	2,050.00	10.0	20600	0.00	0.00	1.00	2,060.00			
Beta-2 microglobulin	Local Lab	650.00	1.0	650	0.00	0.00	0.00	0.00			
LDH	Local Lab	360.00	5.0	1800	0.00	0.00	0.00	0.00			
Uric Acid	Local Lab	240.00	5.0	1200	0.00	0.00	0.00	0.00			
TSH and reflex testing (T3 or free T3 and free T4)	Local Lab	770.00	4.0	3080	0.00	0.00	0.00	0.00			
PT	Local Lab	300.00	1.0	300	0.00	0.00	0.00	0.00			
INR	Local Lab	300.00	1.0	300	0.00	0.00	0.00	0.00			
Blood Sample for sBCMA levels, MRD Tracking, Pfizer Prep D1 retained research samples		950.00	17.0	16150	0.00	0.00	1.00	950.00			
Saliva sample for germline comparator		950.00	1.0	950	0.00	0.00	0.00	0.00			
Study Coordinator - per hour	IRT Registration, Participant ID number, Eligibility criteria, Register with IRT, Randomization, Disease characteristics/treatment history, PROs, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapies, Subsequent anti-cancer therapies/date of progression, survival status, disease response assessment per IMWG criteria, Contraception check, remote / on-site monitoring support, facilities and scheduling	2,453.00	81.9	200900.7	3.20	7,849.60	3.20	7,849.60	4.30	10,547.00	
Blood Sample for circulating proteins and metabolite analysis, TCR sequencing, and immune cell profiling	Arm B	955.00	18.0	17190	0.00	0.00	3.00	2,865.00			
Lenalidomide administration/dispensing	Arm B	1,097.00	17.0	18649	1.03	1,097.00	1.00	1,097.00	1.00	1,097.00	
CMV Testing	Local analysis	2,000.00	1.0	2000	0.00	0.00	0.00	0.00	0.00	0.00	
		PSC Subtotal w/out Overhead		5,31,446.70		15,396.60		9,996.60		33,585.50	
		PSC Subtotal with Overhead		6,37,736.04		18,475.92		11,995.92		40,303.08	





DESCRIPTION OF COST	Comments	COST	Frequency of Procedure	Total Number of times a procedure occurs based on PSC Structure	VISIT 15		VISIT 16		VISIT 17		
					Total PSC	f	C5D1	f	C5D15	f	C6D1
Informed Consent and distribution of ECC		2,448.00	2.0	4896		0.00	0.00	0.00	0.00	0.00	0.00
Demography/medical history		4,000.00	1.0	4000		0.00	0.00	0.00	0.00	0.00	0.00
Physical exam	Includes vital signs, height/weight. Includes comprehensive physical exam at screening.	5,800.00	13.5	78300	1.00	5,800.00		0.00	1.00	5,800.00	
Neurologic exam		5,400.00	18.0	64800	1.00	5,400.00	1.00	5,400.00	1.00	5,400.00	
ICU Score (Encephalopathy assessment)		5,400.00	1.0	5400		0.00	0.00	0.00	0.00	0.00	
ECOG PS		1,045.00	1.0	1045		0.00	0.00	0.00	0.00	0.00	
Tricarboxy 12-Lead ECG		1,500.00	5.0	7500		0.00	0.00	0.00	0.00	0.00	
Single 12-Lead ECG		300.00	1.0	300		0.00	0.00	0.00	0.00	0.00	
Lab handling and shipping of specimens, complex	for central labs	968.00	11.0	10628	1.00	968.00		0.00	1.00	968.00	
SPER, SIFF, FLC	Blood draw for central lab	850.00	11.0	10450	1.00	850.00		0.00	1.00	850.00	
UPEP, UFE	Urine collection for central lab	650.00	11.0	10450	1.00	650.00		0.00	1.00	650.00	
Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	Blood draw for central lab	650.00	11.0	10450	1.00	650.00		0.00	1.00	650.00	
Hematology											
Chemistry	Local Lab	1,050.00	17.0	17850	1.00	1,050.00		0.00	1.00	1,050.00	
	Includes: Blood or BUN Urea, Creatinine, Glucose (non-fasting), Total Calcium, Sodium, Potassium, Chloride, AST, ALT, total bilirubin, Alkaline phosphatase, Albumin. Local lab, Magnesium, Phosphorous or Phosphates	2,060.00	10.0	20600	1.00	2,060.00		0.00	1.00	2,060.00	
Beta-2 microglobulin	Local Lab	650.00	1.0	660		0.00	0.00	0.00	0.00	0.00	
LDH	Local Lab	360.00	5.0	1800		0.00	0.00	0.00	0.00	0.00	
Uric Acid	Local Lab	240.00	5.0	1200		0.00	0.00	0.00	0.00	0.00	
TSH and reflex testing (T2 or free T3 and free T4)	Local Lab	770.00	4.0	3080	1	0.00	0.00	0.00	0.00	0.00	
PT	Local Lab	300.00	1.0	300		0.00	0.00	0.00	0.00	0.00	
INR	Local Lab	300.00	1.0	300		0.00	0.00	0.00	0.00	0.00	
Blood Sample for sBCMA levels, MRD Tracking, Pfizer Prep D1 retained research samples		950.00	17.0	16150	1.00	950.00		0.00	1.00	950.00	
Saliva sample for germline comparator		950.00	1.0	950		0.00	0.00	0.00	0.00	0.00	
Study Coordinator - per hour	IRT Registration, Participant ID number, Eligibility criteria, Register with IRT, Randomization, Disease characteristics/treatment history, PROs, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapies, Subsequent anti-cancer therapies/date of progression, survival status, disease response assessment per IMWG criteria, Contraception check, remote / on-site monitoring support, facilities and scheduling	2,435.00	81.9	200900.7	4.30	10,547.90	3.70	9,078.10	4.30	10,547.90	
Blood Sample for circulating proteins and metabolic analysis, TCR sequencing, and immune cell profiling	Arm B	955.00	18.0	17190	1.00	955.00		0.00	1.00	955.00	
Lenalidomide administration/dispensing	Arm B	1,097.00	17.0	18649	1.00	1,097.00	1.00	1,097.00	1.00	1,097.00	
CMV Testing	Local analysis	2,000.00	1.0	2000		0.00	1.00	0.00	0.00	0.00	
				PSC Subtotal w/out Overhead		5,31,446.70		31,675.90		15,573.10	
				PSC Subtotal with Overhead				38,011.08		18,687.72	
										38,011.08	



DESCRIPTION OF COST	Comments	Frequency of Procedure	Total Number of times a procedure occurs based on PSC Structure	VISIT 18		VISIT 19		VISIT 20		VISIT 21		VISIT 22			
				COST	Total PSC	f	C1D15	f	C1D1	f	EoT	f	FU	f	
Informed Consent and distribution of ECC		2,445.00	2.0	4890		0.00		0.00		0.00		0.00		0.00	
Demography/medical history		4,000.00	1.0	4000		0.00		0.00		0.00		0.00		0.00	
Physical exam	Includes vital signs, height/weight. Includes comprehensive physical exam at screening.	5,800.00	13.5	76300		0.00	1.00	5,800.00	1.00	5,800.00	1.00	5,800.00	1.00	0.00	
Neurologic exam		5,400.00	16.0	86400		1.00	5,400.00	1.00	5,400.00	1.00	5,400.00	1.00	5,400.00	0.00	
ICE Score (Encephalocyst assessment)		5,400.00	1.0	5400		0.00		0.00		0.00		0.00		0.00	
ECG PS		1,045.00	1.0	1045		0.00		0.00		0.00		0.00		0.00	
Triphasic 12-Lead ECG		1,500.00	5.0	7500		0.00		0.00		1,500.00		0.00		0.00	
Single 12-Lead ECG		300.00	1.0	300		0.00		0.00		0.00		0.00		0.00	
Lab handling and shipping of specimens, including shipping	for central lab	968.00	11.0	10626		0.00	1.00	968.00	1.00	966.00		0.00		0.00	
SPER, SIFE, FLC	Blood draw for central lab	950.00	11.0	10450		0.00	1.00	950.00	1.00	950.00	1.00	950.00	1.00	950.00	
UPEP, UFE	Urine collection for central lab	950.00	11.0	10450		0.00	1.00	950.00	1.00	950.00	1.00	950.00	1.00	950.00	
Serum quantifiable immunoglobulins (IgG, IgM, IgA, IgD, IgE)	Blood draw for central lab	250.00	11.0	10450		0.00	1.00	950.00	1.00	950.00	1.00	950.00	1.00	950.00	
Hematology		1,050.00	17.0	17850		0.00	1.00	1,050.00	1.00	1,050.00	1.00	1,050.00	0.00	0.00	
Chemistry	Includes: Blood or BUN Urea, Creatinine, Glucose (non-fasting), Total Calcium, Sodium, Potassium, Chloride, AST, ALT, total bilirubin, Alkaline phosphatase, Albumin, Local lab, Magnesium, Phosphorous or Phosphates	2,060.00	10.0	20600		0.00	1.00	2,060.00	1.00	2,060.00	1.00	2,060.00	0.00	0.00	
Beta-2 microglobulin	Local Lab	600.00	1.0	600		0.00		0.00		0.00		0.00		0.00	
LDH	Local Lab	360.00	5.0	1800		0.00		0.00		0.00		0.00		0.00	
Uric Acid	Local Lab	240.00	5.0	1200		0.00		0.00		0.00		0.00		0.00	
TSH and reflex testing (T3 or free T3 and free T4)	Local Lab	770.00	4.0	3080		0.00	1.00	770.00	1.00	770.00		0.00		0.00	
PT	Local Lab	300.00	1.0	300		0.00		0.00		0.00		0.00		0.00	
INR	Local Lab	300.00	1.0	300		0.00		0.00		0.00		0.00		0.00	
Blood Sample for aSCMA levels, MRD Tracking, Pfizer Prep D1 required research samples		950.00	17.0	16150		0.00	2.00	1,900.00	2.00	1,900.00		0.00		0.00	
Saliva sample for germline comparator		950.00	1.0	950		0.00		0.00		0.00		0.00		0.00	
Study Coordinator - per hour	IRB Registration, Participant ID number, Eligibility criteria, Register with IRB, Randomization, Disease characteristics, Medical history, PROs, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapies, Subsequent anti-cancer therapies/degree of progression, survival status, disease response assessment per IAVG criteria, Contraception check, remote / on-site monitoring support, facilities and scheduling	2,453.00	61.9	20990.7		3.70	9,076.10	4.30	10,547.90	4.30	10,547.90	3.50	8,585.50	1.50	3,679.50
Blood Sample for circulating proteins and metabolite analysis, TCR sequencing, and immune cell profiling	Arm B	955.00	18.0	17190		0.00	1.00	955.00	2.00	1,910.00		0.00		0.00	
Lorazepam administration/dispensing	Arm B	1,097.00	17.0	18649		1.00	1,067.00	1.00	1,097.00		0.00		0.00		0.00
CMV Testing	Local analysis	2,000.00	1.0	2000		0.00		0.00		0.00		0.00		0.00	
	PSC Subtotal with Overhead			5,31,446.70		15,573.10		33,395.90		34,753.90		25,745.50		6,529.50	
	PSC Subtotal with Overhead			6,37,736.04		16,687.72		40,075.08		41,704.68		30,894.60		7,835.40	

	Additional Procedures that may not apply to all Patients	COST	Total Number of times a procedure may occur	Total Potential PSC	f	Pre-Screening (Optional)	f	Screening	f	C1D1
Additional Treatment Related Costs TO BE INVOICED	Serum Pregnancy test	WOCBP (on-site only)	1,000.00	13.0	13000	0.00	1.00	1,000.00	1.00	1,000.00
	Urine Pregnancy test	WOCBP (on-site only)	700.00	13.0	9100	0.00	1.00	700.00	1.00	700.00
	Archival BMA sample for MRD (for clonSeq clonality (ID) Test)	Pre-screening	1,000.00	1.0	1000	1.00	1,000.00		0.00	0.00
	CMV Testing		2,000.00	7.00	14000	0.00	0.00	0.00	1.00	2,000.00
Summary Costs	Per Subject Cost Subtotal		5,31,446.70		8,580.50		49,795.50			43,935.90
	Additional Cost Subtotal				37,100.00		1,700.00			3,700.00
	Subtotal				5,68,546.70		9,580.50			47,635.90
	Overhead				1,13,709.34		1,916.10			9,527.18
	INVESTIGATOR COST PER SUBJECT with Overhead				6,82,256.04		11,495.60			57,163.08

	Additional Procedures that may not apply to all Patients	COST	Total Number of times a procedure may occur	Total Potential PSC	f	C1D8	f	C1D16	f	C1D22
Additional Treatment Related Costs TO BE INVOICED	Serum Pregnancy test	WOCBP (on-site only)	1,000.00	13.0	13000	1.00	1,000.00	1.00	1,000.00	1.00
	Urine Pregnancy test	WOCBP (on-site only)	700.00	13.0	9100	1.00	700.00	1.00	700.00	1.00
	Archival BMA sample for MRD (for clonSeq clonality (ID) Test)	Pre-screening	1,000.00	1.0	1000	0.00	0.00	0.00	1.00	0.00
	CMV Testing		2,000.00	7.00	14000	0.00	0.00	0.00	1.00	0.00
Summary Costs	Per Subject Cost Subtotal		5,31,446.70		19,812.60		28,854.10			16,396.60
	Additional Cost Subtotal				37,100.00		1,700.00			3,700.00
	Subtotal				5,68,546.70		21,512.60			18,095.60
	Overhead				1,13,709.34		4,302.52			3,619.32
	INVESTIGATOR COST PER SUBJECT with Overhead				6,82,256.04		25,816.12			21,716.82



Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	C2D1	f	C2D8	f	C2D15
Additional Treatment Related Costs TO BE INVOICED	Serum Pregnancy test	WOCBP (on-site only)	1,000.00	13.0	13000	1.00	1,000.00		0.00	0.00
	Urine Pregnancy test	WOCBP (on-site only)	700.00	13.0	9100	1.00	700.00		0.00	0.00
	Archival BMA sample for MRD (for clonoSEQ clonality (ID) Test)	Pre-screening	1,000.00	1.0	1000		0.00		0.00	0.00
	CMV Testing		2,000.00	7.00	14000	1.00	2,000.00		0.00	0.00
Summary Costs	Per Subject Cost Subtotal			5,31,446.70	36,080.00	9,996.60		15,396.60		
	Additional Cost Subtotal			37,100.00	3,700.00	0.00		0.00		
	Subtotal			5,68,546.70	38,780.59	9,996.60		15,396.60		
	Overhead			1,13,709.34	7,756.18	1,999.32		3,079.32		
INVESTIGATOR COST PER SUBJECT with Overhead				6,82,256.04	46,537.08	11,995.92		18,475.92		

Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	C2D22	f	C3D1	f	C3D15	f	C4D1
Additional Treatment Related Costs TO BE INVOICED	Serum Pregnancy test	WOCBP (on-site only)	1,000.00	13.0	13000		0.00	1.00	1,000.00		0.00	1.00
	Urine Pregnancy test	WOCBP (on-site only)	700.00	13.0	9100		0.00	1.00	700.00		0.00	1.00
	Archival BMA sample for MRD (for clonoSEQ clonality (ID) Test)	Pre-screening	1,000.00	1.0	1000		0.00		0.00		0.00	
	CMV Testing		2,000.00	7.00	14000	0.00	1.00	2,000.00		0.00	1.00	2,000.00
Summary Costs	Per Subject Cost Subtotal			5,31,446.70	33,586.59	16,623.10		34,896.90				
	Additional Cost Subtotal			37,100.00	3,700.00	0.00		3,700.00				
	Subtotal			5,68,546.70	37,285.59	16,623.10		38,596.90				
	Overhead			1,13,709.34	1,999.32	7,756.18		3,324.62		7,719.18		
INVESTIGATOR COST PER SUBJECT with Overhead				6,82,256.04	11,995.92	46,537.08		19,947.72		46,315.08		

Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	C4D15	f	C5D1	f	C5D15	
Additional Treatment Related Costs TO BE INVOICED	Serum Pregnancy test	WOCBP (on-site only)	1,000.00	13.0	13000		0.00	1.00	1,000.00		0.00
	Urine Pregnancy test	WOCBP (on-site only)	700.00	13.0	9100		0.00	1.00	700.00		0.00
	Archival BMA sample for MRD (for clonoSEQ clonality (ID) Test)	Pre-screening	1,000.00	1.0	1000		0.00		0.00		0.00
	CMV Testing		2,000.00	7.00	14000	0.00	1.00	2,000.00		0.00	0.00
Summary Costs	Per Subject Cost Subtotal			5,31,446.70	15,573.10	31,675.90		15,573.10			
	Additional Cost Subtotal			37,100.00	6,000.00	3,700.00		3,700.00			
	Subtotal			5,68,546.70	35,375.90	15,573.10		37,095.00			
	Overhead			1,13,709.34	3,114.62	7,756.18		3,114.62		9,114.62	
INVESTIGATOR COST PER SUBJECT with Overhead				6,82,256.04	18,687.72	42,451.08		42,451.08		18,687.72	

Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	C6D1	f	C6D15	f	C7D1
Additional Treatment Related Costs TO BE INVOICED	Serum Pregnancy test	WOCBP (on-site only)	1,000.00	13.0	13000	1.00	1,000.00		0.00	1.00
	Urine Pregnancy test	WOCBP (on-site only)	700.00	13.0	9100	1.00	700.00		0.00	1.00
	Archival BMA sample for MRD (for clonoSEQ clonality (ID) Test)	Pre-screening	1,000.00	1.0	1000		0.00		0.00	0.00
	CMV Testing		2,000.00	7.00	14000	1.00	2,000.00		0.00	1.00
Summary Costs	Per Subject Cost Subtotal			5,31,446.70	31,675.90	15,573.10		33,995.90		
	Additional Cost Subtotal			37,100.00	3,700.00	0.00		3,700.00		
	Subtotal			5,68,546.70	35,375.90	15,573.10		37,095.00		
	Overhead			1,13,709.34	7,756.18	3,114.62		7,419.18		
INVESTIGATOR COST PER SUBJECT with Overhead				6,82,256.04	42,451.08	18,687.72		44,515.08		

Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	EoT	f	F/U	f	Long Term F/U Visit
Additional Treatment Related Costs TO BE INVOICED	Serum Pregnancy test	WOCBP (on-site only)	1,000.00	13.0	13000	1.00	1,000.00	1.00	1,000.00	0.00
	Urine Pregnancy test	WOCBP (on-site only)	700.00	13.0	9100	1.00	700.00	1.00	700.00	0.00
	Archival BMA sample for MRD (for clonoSEQ clonality (ID) Test)	Pre-screening	1,000.00	1.0	1000		0.00		0.00	0.00
	CMV Testing		2,000.00	7.00	14000	0.00		0.00		0.00
Summary Costs	Per Subject Cost Subtotal			5,31,446.70	34,752.90	25,745.60		6,529.50		
	Additional Cost Subtotal			37,100.00	3,700.00	1,700.00		1,700.00		
	Subtotal			5,68,546.70	36,453.90	27,445.60		6,529.50		
	Overhead			1,13,709.34	7,290.78	5,489.10		1,305.60		
INVESTIGATOR COST PER SUBJECT with Overhead				6,82,256.04	43,744.68	32,934.66		7,835.40		



Additional Procedures Not included in the Per Subject Cost (Procedures not tied to a specific visit) All Fees Inclusive of Overhead			
Other Study Level Costs	Procedure	Comments	Cost
See Arm A for Administrative Fees, Procedures applicable to all arms and patient compensation			
	Screen Fails	Applicable to subjects who SF at Visit 1. Cost reflects V1 with 25% reduction, no overhead paid. Max 5 SFs per site.	37,346.63
	Day 1: Additional Cycles (starting with C8)	Paid based on EDC data (not invoiceable). Any invoiceables from the Additional Treatment Related Costs section for Cycle 7 costs above may be invoiced additionally as incurred for the cycle (not included in amount listed here).	40,075.08
	Additional LTFU Visits	Paid based on EDC data, per additional LTFU visit	7,835.40
	Pre-Screening Screen Failures	To be invoiced up to total of pre-screening visit. Cap of 5 per site (additional eligible for invoice with prior Pfizer approval)	10,296.60



ARM C

COMPONENT / STUDY NUMBER/ID:	PR. APPROVAL COUNTRY:	ARM/CONTRACT NUMBER:	PI/IC:	INVESTIGATOR: INSTITUTION: COUNTRY:	DR. APPROVAL: NAME/PHONE NUMBER: NA
MONITORING OF ELANATAMAB IN ELANATAMAB (FOLICURE) TREATMENT IN PATIENTS WITH SOLID TUMORS					
COUNTRY/REGION: USA, CA, IND OVERHEAD: 20.0%					

Per Subject Cost

DESCRIPTION OF COST	Comments	COST	Frequency of Procedure	Total PSC	VISIT 1		VISIT 2		VISIT 3	
					f	Pre-Screening (Optional)	f	Screening	f	C101
Informed Consent and distribution of ECC		2,448.00	2.0	4896	1.00	2,448.00	1.00	2,448.00		0.00
Demography/medical history		4,000.00	1.0	4000		0.00	1.00	4,000.00		
Physical exam	Includes vital signs, height/weight. Includes comprehensive physical exam at screening.	5,800.00	10.5	60900		0.00	1.50	8,700.00	1.00	5,800.00
Neurologic exam		5,400.00	10.0	64400		0.00	1.00	5,400.00	1.00	5,400.00
ICE Score (Encephalopathy assessment)		5,400.00	1.0	5400		0.00		0.00	1.00	5,400.00
Vital signs (temperature, HR, BP and O2 saturation)		996.00	19.0	18822		0.00		0.00		0.00
ECOG PS		1,045.00	1.0	1045		0.00	1.00	1,045.00		0.00
Triphasic 12-Lead ECG		1,500.00	5.0	7500		0.00		0.00	1.00	1,500.00
Single 12-Lead ECG		300.00	1.0	300		0.00	1.00	300.00		0.00
Lab handling and shipping of specimens, complex	for central lab	966.00	12.0	11592		0.00	1.00	966.00	1.00	966.00
SPEP, SIFE, FLC	Blood draw for central lab	950.00	11.0	10450		0.00	1.00	950.00	1.00	950.00
UPEP, UFE	Urine collection for central lab	950.00	11.0	10450		0.00	1.00	950.00	1.00	950.00
Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	Blood draw for central lab	950.00	11.0	10450		0.00	1.00	950.00	1.00	950.00
Hematology	Local Lab	1,050.00	17.0	17850		0.00	1.00	1,050.00	1.00	1,050.00
Chemistry	Includes: BUN or Blood Urea, Creatinine, Glucose (non-fasting), Total Calcium, Sodium, Potassium, Chloride, AST, ALT, total bilirubin, Alkaline phosphatase, Albumin. Local lab, Magnesium, Phosphorous or Phosphates	2,060.00	10.0	20600		0.00	1.00	2,060.00	1.00	2,060.00
Beta-2 microglobulin	Local Lab	660.00	1.0	660		0.00	1.00	660.00		0.00
LDH	Local Lab	360.00	6.0	2160		0.00	1.00	360.00	1.00	360.00
Uric Acid	Local Lab	240.00	6.0	1440		0.00	1.00	240.00	1.00	240.00
TSI and reflex testing (T3 or free T3 and free T4)	Local Lab	770.00	4.0	3080		0.00	1.00	770.00		0.00
PT	Local Lab	300.00	1.0	300		0.00	1.00	300.00		0.00
INR	Local Lab	300.00	1.0	300		0.00	1.00	300.00		0.00
Blood sample for PK for elanatamab		865.00	9.0	8555		0.00		0.00	2.00	1,910.00
Blood sample for ADAs and Nabs for elanatamab		865.00	5.0	4775		0.00		0.00	1.00	955.00
Blood Sample for sBCMA levels, MRD Tracking, Pfizer Prep D1 retained research samples		865.00	17.0	15235		0.00	2.00	1,910.00	3.00	2,855.00
Saliva sample for germline comparator		865.00	1.0	855		0.00		0.00	1.00	955.00
Study Coordinator - per hour	number, Eligibility criteria, Register with IRT, Randomization, Disease characteristics/treatment history, PROs, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapies, Subsequent anti-cancer therapies/date of progression, survival status, disease response assessment per IMWG criteria, Contraception check, remote/on-site monitoring support, facilities and scheduling	2,453.00	68.8	2178264	2.50	6,132.50	5.50	13,491.50	4.30	10,547.90
Blood Sample for circulating proteins and metabolite analysis, TCR sequencing, and immune cell profiling		955.00	22.0	21010		0.00	1.00	955.00	3.00	2,855.00
Premedication administration and dispensing for CRS - oral acetaminophen		1,200.00	3.0	3600		0.00		0.00	1.00	1,200.00
Elanatamab administration (injection)		1,303.00	16.0	20648		0.00		0.00	1.00	1,303.00
Elanatamab dispensing (complex)		2,573.00	16.0	41168		0.00		0.00	1.00	2,573.00
CMV Testing	Local analysis	2,000.00	1.0	2000		0.00	1.00	2,000.00		0.00
	PSC Subtotal w/out Overhead			6,15,747.40		8,580.50		48,805.50		50,799.80
	PSC Subtotal with Overhead			7,38,896.88		10,296.60		59,766.60		60,959.68



DESCRIPTION OF COST	Comments	COST	Frequency of Procedure	Total Number of times a procedure occurs based on PSC Structure	VISIT 4		VISIT 5		VISIT 6		
					Total PSC	f	C1D4	f	C1D8	f	C1D15
Informed Consent and distribution of ECC		2,448.00	2.0	4896			0.00	0.00	0.00	0.00	
Demography/medical history		4,000.00	1.0	4000			0.00	0.00	0.00	0.00	
Physical exam	Includes vital signs, height/weight. Includes comprehensive physical exam at screening.	5,800.00	10.5	60900			0.00	0.00	0.00	0.00	
Neurologic exam		5,400.00	16.0	86400			0.00	0.00	1.00	5,400.00	
ICE Score (Encephalopathy assessment)		5,400.00	1.0	5400			0.00	0.00	0.00	0.00	
Vital signs (temperature, HR, BP and O2 saturation)		998.00	19.0	18962	11.00	10,978.00	6.00	5,988.00	1.00	998.00	
ECOG PS		1,045.00	1.0	1045			0.00	0.00	0.00	0.00	
Triphasic 12-Lead ECG		1,500.00	5.0	7500			0.00	1.00	1,500.00	0.00	
Single 12-Lead ECG		300.00	1.0	300			0.00	0.00	0.00	0.00	
Lab handling and shipping of specimens, complex	for central labs	966.00	12.0	11592	1.00	966.00	1.00	966.00	1.00	966.00	
SPEP, SIFE, FLC	Blood draw for central lab	950.00	11.0	10450			0.00	0.00	0.00	0.00	
UPEP, UFE	Urine collection for central lab	950.00	11.0	10450			0.00	0.00	0.00	0.00	
Serum quantitative Immunoglobulins (IgG, IgM, IgA, IgD, IgE)	Blood draw for central lab	950.00	11.0	10450			0.00	0.00	0.00	0.00	
Hematology	Local Lab	1,050.00	17.0	17850			0.00	1.00	1,050.00	1.00	1,050.00
Chemistry	Includes: BUN or Blood Urea, Creatinine, Glucose (non-fasting), Total Calcium, Sodium, Potassium, Chloride, AST, ALT, total bilirubin, Alkaline phosphatase, Albumin. Local lab, Magnesium, Phosphorous or Phosphates	2,060.00	10.0	20600			0.00	0.00	0.00	0.00	
Beta-2 microglobulin	Local Lab	690.00	1.0	690			0.00	0.00	0.00	0.00	
LDH	Local Lab	360.00	6.0	2160	1.00	360.00	1.00	360.00	1.00	360.00	
Uric Acid	Local Lab	240.00	6.0	1440	1.00	240.00	1.00	240.00	1.00	240.00	
TSH and reflex testing (T3 or free T3 and free T4)	Local Lab	770.00	4.0	3080			0.00	0.00	0.00	0.00	
PT	Local Lab	300.00	1.0	300			0.00	0.00	0.00	0.00	
INR	Local Lab	300.00	1.0	300			0.00	0.00	0.00	0.00	
Blood sample for PK for elranatamab		955.00	9.0	8505	2.00	1,910.00	1.00	955.00	0.00		
Blood sample for ADAs and Nabs for elranatamab		955.00	5.0	4775			0.00	0.00	0.00	0.00	
Blood Sample for sBCMA levels, MRD Tracking, Pfizer Prep D1 retained research samples		955.00	17.0	16295			0.00	1.00	955.00	0.00	
Saliva sample for germline comparator		955.00	1.0	955			0.00	0.00	0.00	0.00	
Study Coordinator - per hour	number, Eligibility criteria, Register with IRT, Randomization, Disease characteristics/treatment history, PROs, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapies, Subsequent anti-cancer therapies/date of progression, survival status, disease response assessment per IMWG criteria, Contraception check, remote / on-site monitoring support, facilities and scheduling	2,453.00	88.8	217826.4	3.20	7,849.60	3.20	7,849.60	3.70	9,076.10	
Blood Sample for circulating proteins and metabolite analysis, TCR sequencing, and immune cell profiling		955.00	22.0	21010	2.00	1,910.00	2.00	1,910.00	3.00	2,865.00	
Premedication administration and dispensing for CRS - oral acetaminophen		1,200.00	3.0	3600	1.00	1,200.00	1.00	1,200.00	0.00		
Elranatamab administration (injection)		1,303.00	16.0	20848	1.00	1,303.00	1.00	1,303.00	1.00	1,303.00	
Elranatamab dispensing (complex)		2,573.00	16.0	41168	1.00	2,573.00	1.00	2,573.00	1.00	2,573.00	
CMV Testing	Local analysis	2,000.00	1.0	2000			0.00	0.00	0.00	0.00	
	PSC Subtotal w/out Overhead			6,15,747.40		29,269.60		26,849.60		24,831.10	
	PSC Subtotal with Overhead			7,38,895.88		35,147.52		32,219.52		29,797.32	



DESCRIPTION OF COST	Comments	COST	Frequency of Procedure	Total Number of times a procedure occurs based on PSC Structure	Total PSC	VISIT 7		VISIT 8		VISIT 9	
						f	C1D22	f	C2D1	f	C2D8
Informed Consent and distribution of ECC		2,448.00	2.0	4896		0.00		0.00		0.00	
Demography/medical history		4,000.00	1.0	4000		0.00		0.00		0.00	
Physical exam	Includes vital signs, height/weight, includes comprehensive physical exam at screening	5,800.00	10.5	60500		0.00	1.00	5,800.00		0.00	
Neurologic exam		5,400.00	16.0	86400		0.00	1.00	5,400.00		0.00	
ICE Score (Encephalopathy assessment)		5,400.00	1.0	5400		0.00		0.00		0.00	
Vital signs (temperature, HR, BP and O2 saturation)		998.00	19.0	18962	1.00	998.00		0.00		0.00	
ECOG PS		1,045.00	1.0	1045		0.00		0.00		0.00	
Tripletate 12-Lead ECG		1,500.00	5.0	7500		0.00	1.00	1,500.00		0.00	
Single 12-Lead ECG		300.00	1.0	300		0.00		0.00		0.00	
Lab handling and shipping of specimens, complex	for central labs	996.00	12.0	11592		0.00	1.00	996.00		0.00	
SPER_SIFE_FLC	Blood draw for central lab	650.00	11.0	10450		0.00	1.00	650.00		0.00	
UPEP_UFE	Urine collection for central lab	950.00	11.0	10450		0.00	1.00	950.00		0.00	
Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	Blood draw for central lab	950.00	11.0	10450		0.00	1.00	950.00		0.00	
Hematology	Local Lab	1,050.00	17.0	17850	1.00	1,050.00	1.00	1,050.00	1.00	1,050.00	
Chemistry	Includes BUN/urine Blood Urea, Creatinine, Glucose (non-fasting), Total Calcium, Sodium, Potassium, Chloride, AST, ALT, total bilirubin, Alkaline phosphatase, Albumin, Local lab, Magnesium, Phosphorous or Phosphates	2,060.00	10.0	20600		0.00	1.00	2,060.00		0.00	
Beta-2 microglobulin	Local Lab	660.00	1.0	660		0.00		0.00		0.00	
LDH	Local Lab	350.00	6.0	2160	1.00	350.00		0.00		0.00	
Uric Acid	Local Lab	240.00	6.0	1440	1.00	240.00		0.00		0.00	
TSH and reflex testing (T3 or free T3 and free T4)	Local Lab	770.00	4.0	3080		0.00		0.00		0.00	
PT	Local Lab	300.00	1.0	300		0.00		0.00		0.00	
INR	Local Lab	300.00	1.0	300		0.00		0.00		0.00	
Blood sample for PK for eranatramab		955.00	9.0	8595		0.00	1.00	855.00		0.00	
Blood sample for ADAs and Nabs for eranatramab		955.00	5.0	4775		0.00	1.00	955.00		0.00	
Blood Sample for sBCMA levels, MRI Tracking, Pfizer Prep D1 retained research samples		955.00	17.0	16235		0.00	2.00	1,910.00		0.00	
Saliva sample for germline comparator		955.00	1.0	955		0.00		0.00		0.00	
Study Coordinator - per hour	number, Eligibility criteria, Register with IRT, Randomization, Disease characteristics/treatment history, POCs, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapies, Subsequent anti-cancer therapies/date of progression, survival status, disease response assessment per IMWG criteria, Contraception check, remote / on-site monitoring support, facilities and scheduling	2,453.00	88.8	217826.4	3.20	7,849.60	4.30	10,547.90	3.20	7,849.60	
Blood Sample for circulating proteins and metabolite analysis, TCR sequencing, and immune cell profiling		955.00	22.0	21010		0.00	2.00	1,910.00		0.00	
Premedication administration and dispensing for CRS - oral acetaminophen		1,200.00	3.0	3600		0.00		0.00		0.00	
Eranatramab administration (injection)		1,303.00	16.0	20848		0.00	1.00	1,303.00		0.00	
Eranatramab dispensing (complex)		2,573.00	16.0	41168		0.00	1.00	2,573.00		0.00	
CMV Testing	Local analysis	2,000.00	1.0	2000		0.00		0.00		0.00	
	PSC Subtotal w/out Overhead			6,15,747.40		10,497.60		39,779.90		8,869.60	
	PSC Subtotal with Overhead			7,38,896.68		12,597.12		47,735.88		10,579.52	



DESCRIPTION OF COST	Comments	Frequency of Procedure	COST	Total Number of times a procedure occurs based on PSC Structure	VISIT 10		VISIT 11		VISIT 12		
					Total PSC	f	C2D15	f	C2D22	f	C3D1
Informed Consent and distribution of ECC		2,448.00	2.0	4896		0.00		0.00		0.00	
Demography/medical history		4,000.00	1.0	4000		0.00		0.00		0.00	
Physical exam	Includes vital signs, height/weight, includes comprehensive physical exam at screening	5,800.00	10.5	60900		0.00		0.00	1.00	5,800.00	
Neurologic exam		5,400.00	16.0	86400	1.00	5,400.00		0.00	1.00	5,400.00	
ECOG Score (Encephalopathy assessment)		5,400.00	1.0	5400		0.00		0.00		0.00	
Vital signs (temperature, HR, BP and O2 saturation)		998.00	19.0	18962		0.00		0.00		0.00	
ECOG PS		1,045.00	1.0	1045		0.00		0.00		0.00	
Triphasic 12-Lead ECG		1,500.00	5.0	7500		0.00		0.00		0.00	
Single 12-Lead ECG		300.00	1.0	300		0.00		0.00		0.00	
Lab handling and shipping of specimens											
complex	for central labs	958.00	12.0	11592		0.00		0.00	1.00	958.00	
SPPE, SIFE, FLC	Blood draw for central lab	950.00	11.0	10450		0.00		0.00	1.00	950.00	
UPEP, UFE	Urine collection for central lab	950.00	11.0	10450		0.00		0.00	1.00	950.00	
Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	Blood draw for central lab	950.00	11.0	10450		0.00		0.00	1.00	950.00	
Hematology	Local Lab	1,050.00	17.0	17850	1.00	1,050.00	1.00	1,050.00	1.00	1,050.00	
Chemistry	Includes: BUN or Blood Urea, Creatinine, Glucose (non-fasting), Total Calcium, Sodium, Potassium, Chloride, AST, ALT, total bilirubin, Alkaline phosphatase, Albumin, Local Iso, Magnesium, Phosphorous or Phosphates	2,060.00	10.0	20600		0.00		0.00	1.00	2,060.00	
Beta-2 microglobulin	Local Lab	560.00	1.0	660		0.00		0.00		0.00	
LDH	Local Lab	350.00	6.0	2150		0.00		0.00		0.00	
Uric Acid	Local Lab	240.00	6.0	1440		0.00		0.00		0.00	
TSH and reflex testing (T3 or free T3 and free T4)	Local Lab	770.00	4.0	3080		0.00		0.00		0.00	
PT	Local Lab	300.00	1.0	300		0.00		0.00		0.00	
INR	Local Lab	300.00	1.0	300		0.00		0.00		0.00	
Blood sample for PK for elanatamab		955.00	9.0	8595		0.00		0.00		0.00	
Blood sample for ADAs and Nabs for elanatamab		955.00	5.0	4775		0.00		0.00		0.00	
Blood Sample for sBCMA levels, MRD Tracking, Pfizer Prep D1 retained research samples		955.00	17.0	16235		0.00		0.00	1.00	955.00	
Saliva sample for germline comparator		955.00	1.0	955		0.00		0.00		0.00	
Study Coordinator - per hour	number, Eligibility criteria, Register w/ IRT, Randomization, Disease characteristics/treatment history, PROs, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapies, Subsequent anti-cancer therapies/date of progression, survival status, disease response assessment per IMWG criteria, Contraception check, remote / on-site monitoring support, facilities and scheduling	2,453.00	88.8	217826.4	3.20	7,849.60	3.20	7,849.60	4.30	10,547.90	
Blood Sample for circulating proteins and metabolite analysis, TCR sequencing, and immune cell profiling		955.00	22.0	21010		0.00		0.00	3.00	2,865.00	
Premedication administration and dispensing for CRS - oral acetaminophen		1,200.00	3.0	3600		0.00		0.00		0.00	
Elanatamab administration (injection)		1,303.00	15.0	20848	1.00	1,323.00		0.00	1.00	1,303.00	
Elanatamab dispensing (complex)		2,573.00	16.0	41168	1.00	2,573.00		0.00	1.00	2,573.00	
CMV Testing	Local analysis	2,000.00	1.0	2000		0.00		0.00		0.00	
	PSG Subtotal w/out Overhead			6,15,747.40		16,175.60		8,899.60		36,369.90	
	PSG Subtotal with Overhead			7,38,896.88		21,810.72		10,679.52		43,643.88	



DESCRIPTION OF COST	Comments	COST	Frequency of Procedure Total Number of times a procedure occurs based on PSC Structure	Total PSC	VISIT 13		VISIT 14		VISIT 15	
					f	C3D15	f	C4D1	f	C4D15
Informed Consent and distribution of ECC		2,448.00	2.0	4896		0.00	0.00	0.00	0.00	0.00
Demography/medical history		4,000.00	1.0	4000		0.00	0.00	0.00	0.00	0.00
Physical exam	Includes vital signs, height/weight. Includes comprehensive physical exam at screening	5,800.00	10.5	60900		0.00	1.00	5,800.00	0.00	0.00
Neurologic exam		5,400.00	15.0	66400	1.00	5,400.00	1.00	5,400.00	1.00	5,400.00
ICE Score (Encephalopathy assessment)		5,400.00	1.0	5400		0.00	0.00	0.00	0.00	0.00
Vital signs (temperature, HR, BP and O2 saturator)		996.00	19.0	1892		0.00	0.00	0.00	0.00	0.00
ECOG PS		1,045.00	1.0	1045		0.00	0.00	0.00	0.00	0.00
Triplelate 12-Lead ECG		1,500.00	5.0	7500		0.00	1.00	1,500.00	0.00	0.00
Single 12-Lead ECG		300.00	1.0	300		0.00	0.00	0.00	0.00	0.00
Lab handling and shipping of specimens, complex	for central lab	956.00	12.0	11592		0.00	1.00	956.00	0.00	0.00
SPEP, SIFE, FLC	Blood draw for central lab	950.00	11.0	10450		0.00	1.00	950.00	0.00	0.00
UPEP, UIFE	Urine collection for central lab	950.00	11.0	10450		0.00	1.00	950.00	0.00	0.00
Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	Blood draw for central lab	950.00	11.0	10450		0.00	1.00	950.00	0.00	0.00
Hematology	Local Lab	1,050.00	17.0	17850	1.00	1,050.00	1.00	1,050.00	0.00	0.00
Chemistry	Includes: BUN or Blood Urea, Creatinine, Glucose (non-fasting), Total Calcium, Sodium, Potassium, Chloride, AST, ALT, total bilirubin, Alkaline phosphatase, Albumin, Local lab, Magnesium, Phosphorous or Phosphates	2,060.00	10.0	20600		0.00	1.00	2,060.00	0.00	0.00
Beta-2 microglobulin	Local Lab	660.00	1.0	660		0.00	0.00	0.00	0.00	0.00
LDH	Local Lab	360.00	6.0	2160		0.00	0.00	0.00	0.00	0.00
Uric Acid	Local Lab	240.00	6.0	1440		0.00	0.00	0.00	0.00	0.00
TSH and reflex testing (T3 or free T3 and free T4)	Local Lab	770.00	4.0	3080		0.00	1.00	770.00	0.00	0.00
PT	Local Lab	300.00	1.0	300		0.00	0.00	0.00	0.00	0.00
INR	Local Lab	300.00	1.0	300		0.00	0.00	0.00	0.00	0.00
Blood sample for PK for eranatamab		955.00	9.0	8595		0.00	1.00	955.00	0.00	0.00
Blood sample for ADAAs and Nabe for eranatamab		955.00	5.0	4775		0.00	1.00	955.00	0.00	0.00
Blood Sample for sBCMA levels, MRD Tracking, Pfizer Prep D1 retained research samples		955.00	17.0	15235		0.00	2.00	1,910.00	0.00	0.00
Saliva sample for germline comparator		955.00	1.0	955		0.00	0.00	0.00	0.00	0.00
Study Coordinator - per hour	number, Eligibility criteria, Register with IRT, Randomization, Disease characteristics/treatment history, PRCs, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapies, Subsequent anti-cancer therapies/date of progression, survival status, disease response assessment per IMWG criteria, Contraception check, remote / on-site monitoring support, facilitates and scheduling	2,453.00	88.8	217826.4	3.70	9,076.10	4.30	10,547.90	3.70	9,076.10
Blood Sample for circulating proteins and metabolite analysis, TCR sequencing, and immune cell profiling		655.00	22.0	21010		0.00	1.00	655.00	0.00	0.00
Premedication administration and dispensing for CRS - oral acetaminophen		1,200.00	3.0	3600		0.00	0.00	0.00	0.00	0.00
Eranatamab administration (injection)		1,303.00	16.0	20848	1.00	1,303.00	1.00	1,303.00	1.00	1,303.00
Eranatamab dispensing (complex)		2,573.00	16.0	41168	1.00	2,573.00	1.00	2,573.00	1.00	2,573.00
CMV Testing	Local analysis	2,000.00	1.0	2000		0.00	0.00	0.00	0.00	0.00
	PSC Subtotal w/out Overhead			6,157,474.40		19,402.10		39,594.90		18,352.10
	PSC Subtotal with Overhead			7,38,896.88		23,282.52		47,513.88		22,022.52



DESCRIPTION OF COST	Comments	COST	Frequency of Procedure	Total Number of times a procedure occurs based on PSC Structure	VISIT 16		VISIT 17		VISIT 18	
					Total PSC	f	CSD1	f	CSD15	f
Informed Consent and distribution of ECC		2,448.00	2.0	4896			0.00	0.00	0.00	0.00
Demography/medical history		4,000.00	1.0	4000			0.00	0.00	0.00	0.00
Physical exam	Includes vital signs, height/weight, Includes comprehensive physical exam at screening	5,800.00	10.5	60900	1.00	5,800.00	0.00	1.00	5,800.00	0.00
Neurologic exam		5,400.00	16.0	86400	1.00	5,400.00	1.00	5,400.00	1.00	5,400.00
ICE Score (Encephalopathy assessment)		5,400.00	1.0	5400		0.00	0.00	0.00	0.00	0.00
Vital signs (temperature, HR, BP and O2 saturation)		998.00	19.0	1892		0.00	0.00	0.00	0.00	0.00
ECG6 PS		1,045.00	1.0	1045		0.00	0.00	0.00	0.00	0.00
Triphasic 12-Lead ECG		1,500.00	5.0	7500		0.00	0.00	0.00	0.00	0.00
Single 12-Lead ECG		300.00	1.0	300		0.00	0.00	0.00	0.00	0.00
Lab handling and shipping of specimens, complex	for central labs	656.00	12.0	11592	1.00	656.00	0.00	1.00	656.00	0.00
SPER, SIFE, FLC	Blood draw for central lab	950.00	11.0	10450	1.00	950.00	0.00	1.00	950.00	0.00
UPEP, UIFE	Urine collection for central lab	950.00	11.0	10450	1.00	950.00	0.00	1.00	950.00	0.00
Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	Blood draw for central lab	950.00	11.0	10450	1.00	950.00	0.00	1.00	950.00	0.00
Hematology	Local Lab	1,050.00	17.0	17850	1.00	1,050.00	0.00	1.00	1,050.00	0.00
Chemistry	Includes: BUN or Blood Urea, Creatinine, Glucose (non-fasting), Total Calcium, Sodium, Potassium, Chloride, AST, ALT, total bilirubin, Alkaline phosphatase, Albumin, Local lab, Magnesium, Phosphorous or Phosphates	2,060.00	10.0	20600	1.00	2,060.00	0.00	1.00	2,060.00	0.00
Beta-2 microglobulin	Local Lab	660.00	1.0	660		0.00	0.00	0.00	0.00	0.00
LDH	Local Lab	350.00	6.0	2150		0.00	0.00	0.00	0.00	0.00
Uric Acid	Local Lab	240.00	6.0	1440		0.00	0.00	0.00	0.00	0.00
TSH and reflex testing (T3 or free T3 and free T4)	Local Lab	770.00	4.0	3080		0.00	0.00	0.00	0.00	0.00
PT	Local Lab	300.00	1.0	300		0.00	0.00	0.00	0.00	0.00
INR	Local Lab	300.00	1.0	300		0.00	0.00	0.00	0.00	0.00
Blood sample for PK for eranatimab		855.00	9.0	8595		0.00	0.00	0.00	0.00	0.00
Blood sample for ADAs and Nabs for eranatimab		855.00	5.0	4775		0.00	0.00	0.00	0.00	0.00
Blood Sample for sBCMA levels, MRD Tracking, Pfizer PreP D1 retained research samples		955.00	17.0	16235	1.00	955.00	0.00	1.00	955.00	0.00
Saliva sample for germline comparator		955.00	1.0	955		0.00	0.00	0.00	0.00	0.00
number, Eligibility criteria, Register with IRT, Randomization, Disease characteristics/treatment history, PROs, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapies, Subsequent anti-cancer therapies/date of progression, survival status, disease response assessment per IMWG criteria, Contraception check, remote / on-site monitoring support, facilities and scheduling										
Study Coordinator - per hour		2,453.00	68.6	217826.4	4.30	10,547.90	3.70	9,076.10	4.30	10,547.90
Blood Sample for circulating proteins and metabolic analysis, TCR sequencing, and immune cell profiling		955.00	22.0	21010	1.00	955.00	0.00	1.00	955.00	0.00
Premedication administration and dispensing for CRS - oral acetaminophen		1,200.00	3.0	3600		0.00	0.00	0.00	0.00	0.00
Eranatimab administration (injection)		1,303.00	16.0	20848	1.00	1,503.00	1.00	1,203.00	1.00	1,393.00
Eranatimab dispensing (complex)		2,573.00	16.0	41168	1.00	2,573.00	1.00	2,573.00	1.00	2,573.00
CMV Testing	Local analysis	2,000.00	1.0	2000		0.00	0.00	0.00	0.00	0.00
	PSC Subtotal without Overhead			6,15,747.40		34,459.90		18,352.10		34,459.90
	PSC Subtotal with Overhead			7,38,896.86		41,351.88		22,022.52		41,351.88



DESCRIPTION OF COST	Comments	COST	Frequency of Procedure	Total Number of times a procedure occurs based on PSC Structure	VISIT 19		VISIT 20		VISIT 21		
					Total PSC	f	C6D15	f	C7D1	f	C7D15
Informed Consent and distribution of ECC		2,448.00	2.0	4896		0.00		0.00		0.00	
Demographic/medical history		4,000.00	1.0	4000		0.00		0.00		0.00	
Physical exam	Includes vital signs, height/weight. Includes comprehensive physical exam at screening.	5,800.00	10.5	60900		0.00	1.00	5,600.00		0.00	
Neurologic exam		5,400.00	16.0	66400	1.00	5,400.00	1.00	5,400.00		0.00	
ICE Score (Encephalopathy assessment)		5,400.00	1.0	5400		0.00		0.00		0.00	
Vital signs (temperature, HR, BP and O2 saturation)		998.00	19.0	1892		0.00		0.00		0.00	
ECOG PS		1,045.00	1.0	1045		0.00		0.00		0.00	
Tricigate 12-Lead ECG		1,500.00	5.0	7500		0.00		0.00		0.00	
Single 12-Lead ECG		300.00	1.0	300		0.00		0.00		0.00	
Lab handling and shipping of specimens, complex	for central labs	956.00	12.0	11592		0.00	1.00	956.00		0.00	
SPEP, SIFE, FLC	Blood draw for central lab	950.00	11.0	10450		0.00	1.00	950.00		0.00	
UPER, UFE	Urine collection for central lab	950.00	11.0	10450		0.00	1.00	950.00		0.00	
Serum quantifiable immunoglobulins (IgG, IgM, IgA, IgD, IgE)	Blood draw for central lab	950.00	11.0	10450		0.00	1.00	950.00		0.00	
Hematology	Local Lab	1,050.00	17.0	17850		0.00	1.00	1,050.00		0.00	
Chemistry	Includes: BUN or Blood Urea, Creatinine, Glucose (non-fasting), Total Calcium, Sodium, Potassium, Chloride, AST, ALT, total bilirubin, Alkaline phosphatase, Albumin, Local lab, Magnesium, Phosphorous or Phosphates	2,080.00	10.0	20600		0.00	1.00	2,060.00		0.00	
Beta-2 microglobulin	Local Lab	550.00	1.0	660		0.00		0.00		0.00	
LDH	Local Lab	360.00	6.0	2160		0.00		0.00		0.00	
Uric Acid	Local Lab	240.00	6.0	1440		0.00		0.00		0.00	
TSH and reflex testing (T3 or free T3 and free T4)	Local Lab	770.00	4.0	3080		0.00	1.00	770.00		0.00	
PT	Local Lab	300.00	1.0	300		0.00		0.00		0.00	
INR	Local Lab	300.00	1.0	300		0.00		0.00		0.00	
Blood sample for PK for elanatamab		955.00	9.0	8595		0.00	1.00	955.00		0.00	
Blood sample for ADAs and Nabs for elanatamab		955.00	5.0	4775		0.00	1.00	955.00		0.00	
Blood Sample for sBCMA levels, MRD Tracking, Pfizer Prep D1 retained research samples		955.00	17.0	16235		0.00	2.00	1,910.00		0.00	
Saliva sample for germline comparator		955.00	1.0	955		0.00		0.00		0.00	
Study Coordinator - per hour	number, Eligibility criteria, Register with IRT, Randomization, Disease characteristics/treatment history, PROs, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapies, Subsequent anti-cancer therapies/date of progression, survival status, disease response assessment per IMWG criteria, Contraception check, remote / on-site monitoring support, facilities and scheduling	2,453.00	88.8	217826.4	3.70	9,076.10	4.30	10,547.50	3.70	8,076.10	
Blood Sample for circulating proteins and metabolic analysis, TCR sequencing, and immune cell profiling		955.00	22.0	21010		0.00	1.00	955.00		0.00	
Premedication administration and dispensing for CRS - oral acetaminophen		1,200.00	3.0	3600		0.00		0.00		0.00	
Elanatamab administration (injection)		1,303.00	15.0	20848	1.00	1,303.00	1.00	1,303.00	1.00	1,303.00	
Elanatamab dispensing (complex)		2,573.00	15.0	41168	1.00	2,573.00	1.00	2,573.00	1.00	2,573.00	
CMV Testing	Local analysis	2,000.00	1.0	2000		0.00		0.00		0.00	
	PSC Subtotal without Overhead			6,15,747.40		18,352.10		38,094.90		12,952.10	
	PSC Subtotal with Overhead			7,38,896.88		22,022.52		45,713.88		15,542.52	



DESCRIPTION OF COST	Comments	COST	Frequency of Procedure	Total Number of times a procedure occurs based on PSC Structure	VISIT 22		VISIT 23		VISIT 24		
					Total PSC	f	EoT	f	F/U	f	Long Term F/U Visit
Informed Consent and distribution of ECC		2,448.00	2.0	4896		0.00		0.00		0.00	
Demography/medical history		4,000.00	1.0	4000		0.00		0.00		0.00	
Physical exam	Includes vital signs, height/weight, Includes comprehensive physical exam at screening.	5,800.00	10.5	60900	1.00	5,800.00	1.00	5,800.00		0.00	
Neurology exam		5,400.00	16.0	86400	1.00	5,400.00	1.00	5,400.00		0.00	
ICE Score (Encephalopathy assessment)		5,400.00	1.0	5400		0.00		0.00		0.00	
Vital signs (temperature, HR, BP and O2 saturation)		998.00	19.0	18962		0.00		0.00		0.00	
ECOG PS		1,045.00	1.0	1045		0.00		0.00		0.00	
Triphasic 12-Lead ECG		1,500.00	5.0	7500	1.00	1,500.00		0.00		0.00	
Single 12-Lead ECG		300.00	1.0	300		0.00		0.00		0.00	
Lab handling and shipping of specimens, complex	for central labs	968.00	12.0	11592	1.00	966.00		0.00		0.00	
SPEP, SIFE, FLC	Blood draw for central lab	950.00	11.0	10450	1.00	950.00	1.00	950.00	1.00	950.00	
UPEP, UFE	Urine collection for central lab	950.00	11.0	10450	1.00	950.00	1.00	950.00	1.00	950.00	
Serum quantitative immunoglobulins (IgG, IgM, IgA, IgD, IgE)	Blood draw for central lab	950.00	11.0	10450	1.00	950.00	1.00	950.00	1.00	950.00	
Hematology	Local Lab	1,050.00	17.0	17850	1.00	1,050.00	1.00	1,050.00		0.00	
Chemistry	Includes: BUN or Blood Urea, Creatinine, Glucose (non-fasting), Total Calcium, Sodium, Potassium, Chloride, AST, ALT, total bilirubin, Alkaline phosphatase, Albumin, Local lab, Magnesium, Phosphorous or Phosphates	2,060.00	10.0	20600	1.00	2,060.00	1.00	2,060.00		0.00	
Beta-2 microglobulin	Local Lab	660.00	1.0	660		0.00		0.00		0.00	
LDH	Local Lab	360.00	6.0	2160		0.00		0.00		0.00	
Uric Acid	Local Lab	240.00	6.0	1440		0.00		0.00		0.00	
TSH and reflex testing (T3 or free T3 and free T4)	Local Lab	770.00	4.0	3080	1.00	770.00		0.00		0.00	
PT	Local Lab	300.00	1.0	300		0.00		0.00		0.00	
INR	Local Lab	300.00	1.0	300		0.00		0.00		0.00	
Blood sample for PK for eranatamab		955.00	9.0	8595	1.00	955.00		0.00		0.00	
Blood sample for ADAs and Nabs for eranatamab		955.00	5.0	4775	1.00	955.00		0.00		0.00	
Blood Sample for sBCMA levels, MRD Tracking, Pfizer Prep D1 retained research samples		955.00	17.0	16235	2.00	1,910.00		0.00		0.00	
Saliva sample for germline comparator		955.00	1.0	955		0.00		0.00		0.00	
Study Coordinator - per hour	number. Eligibility criteria. Register with IRT, Randomization, Disease characteristics/treatment history, FROs, Healthcare resource use, Serious and nonserious AE monitoring, Concomitant therapies, Subsequent anti-cancer therapies/date of progression, survival status, disease response assessment per IMWG criteria, Contraception check, remote / on-site monitoring support, facilities and scheduling	2,453.00	88.8	217826.4	4.30	10,547.90	3.50	8,585.50	1.50	3,679.50	
Blood Sample for circulating proteins and metabolic analysis, TCR sequencing, and immune cell profiling		955.00	22.0	21010	2.00	1,910.00		0.00		0.00	
Premedication administration and dispensing for CRS - oral acetaminophen		1,200.00	3.0	3600		0.00		0.00		0.00	
Eranatamab administration (injection)		1,303.00	16.0	20848		0.00		0.00		0.00	
Eranatamab dispensing (complex)		2,573.00	16.0	41168		0.00		0.00		0.00	
CMV Testing	Local analysis	2,000.00	1.0	2000		0.00		0.00		0.00	
	PSC Subtotal w/out Overhead				6,15,747.40		36,673.90		25,745.50		6,529.50
	PSC Subtotal with Overhead				7,38,895.88		44,008.68		30,894.60		7,835.40

	Additional Procedures that may not apply to all Patients	COST	Total Number of times a procedure may occur	Total Potential PSC	f	Pre-Screening (Optional)	f	Screening	f	C1D1
Additional Treatment Related Costs										
TO BE INVOICED	Serum Pregnancy test, Urine Pregnancy test, Premedication for eranatamab - administration and dispensing (if oral), Premedication for eranatamab - administration and dispensing (if IV), Premedication for eranatamab - dispensing (IV) (complex), Archival BMA sample for MRD (for clonoSEQ clonality (ID) Test), CMV testing	WOCBP (on-site only) 1,000.00 WOCBP (on-site only) 703.00 Diphenhydramine and Dexamethasone 1,200.00 Diphenhydramine and Dexamethasone 4,597.00 Diphenhydramine and Dexamethasone 2,573.00 Pre-screening 1,000.00 Local analysis 2,000.00	13.0 13.0 6.0 6.0 6.0 1.0 7.00	13000 9100 7200 20882 15436 1000 14000		0.00 0.00 0.00 0.00 0.00 1.00 0.00	1.00 1.00 2.00 2.00 2.00 1.00 1.00	1,000.00 700.00 1,200.00 8,550.50 9,530.50 1,000.00 2,000.00	1,000.00 700.00 1,200.00 8,550.50 9,530.50 1,000.00 2,000.00	1,000.00 700.00 1,200.00 8,550.50 9,530.50 1,000.00 2,000.00
Summary Costs	Per Subject Cost Subtotal Additional Cost Subtotal Subtotal Overhead INVESTIGATOR COST PER SUBJECT with Overhead			6,15,747.40 89,720.00 7,05,467.40 1,41,093.48 8,44,560.88		8,550.50 1,000.00 9,530.50 1,918.10 11,496.60		49,805.50 1,700.00 51,505.50 10,301.10 61,804.60		50,799.50 21,243.00 72,039.50 14,407.98 56,447.88

263708 C1071007 IND 1284 CSA Verma English 20230411 1.0



Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	C1D4	f	C1D8	f	C1D15
TO BE INVOICED	Serum Pregnancy test	WOCBP (on-site only)	1,000.00	13.0	13000		0.00	1.00	1,000.00	1.00
	Urine Pregnancy test	WOCBP (on-site only)	700.00	13.0	9100		0.00	1.00	700.00	1.00
	Premedication for etanercept - administration and dispensing (if oral)	Diphenhydramine and Dexamethasone	1,200.00	6.0	7200	2.00	2,400.00	2.00	2,400.00	0.00
	Premedication for etanercept - administration (if IV)	Diphenhydramine and Dexamethasone	4,997.00	6.0	29982	2.00	9,994.00	2.00	9,994.00	0.00
	Premedication for etanercept - dispensing (IV) (complex)	Diphenhydramine and Dexamethasone	2,573.00	6.0	15438	2.00	5,146.00	2.00	5,146.00	0.00
	Archival BMA sample for MRD (for cloneSEQ clonality (ID) Test)	Pre-screening	1,000.00	1.0	1000		0.00	0.00	0.00	0.00
	CMV testing	Local analysis	2,000.00	7.00	14000		0.00	0.00	0.00	0.00
	Per Subject Cost Subtotal			6,15,747.40		29,289.60		26,549.60		24,831.10
	Additional Cost Subtotal			89,720.00		17,540.00		19,242.00		1,700.00
	Subtotal			7,05,467.40		46,829.60		45,066.60		29,531.10
Summary Costs	Overhead			1,41,093.48		3,635.92		9,217.92		5,300.22
	INVESTIGATOR COST PER SUBJECT with Overhead			8,46,560.88		56,195.52		55,207.62		31,827.12

Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	C1D22	f	C2D1	f	C2D8
TO BE INVOICED	Serum Pregnancy test	WOCBP (on-site only)	1,000.00	13.0	13000	1.00	1,000.00	1.00	1,000.00	0.00
	Urine Pregnancy test	WOCBP (on-site only)	700.00	13.0	9100	1.00	700.00	1.00	700.00	0.00
	Premedication for etanercept - administration and dispensing (if oral)	Diphenhydramine and Dexamethasone	1,200.00	6.0	7200		0.00	0.00	0.00	0.00
	Premedication for etanercept - administration (if IV)	Diphenhydramine and Dexamethasone	4,997.00	6.0	29982		0.00	0.00	0.00	0.00
	Premedication for etanercept - dispensing (IV) (complex)	Diphenhydramine and Dexamethasone	2,573.00	6.0	15438		0.00	0.00	0.00	0.00
	Archival BMA sample for MRD (for cloneSEQ clonality (ID) Test)	Pre-screening	1,000.00	1.0	1000		0.00	0.00	0.00	0.00
	CMV testing	Local analysis	2,000.00	7.00	14000		0.00	1.00	2,000.00	0.00
	Per Subject Cost Subtotal			6,15,747.40		10,497.60		39,779.00		8,899.60
	Additional Cost Subtotal			89,720.00		1,700.00		3,700.00		0.00
	Subtotal			7,05,467.40		12,197.60		43,479.90		8,899.60
Summary Costs	Overhead			1,41,093.48		2,430.52		8,095.98		1,779.92
	INVESTIGATOR COST PER SUBJECT with Overhead			8,46,560.88		14,637.12		52,175.98		10,679.52

Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	C2D15	f	C2D22	f	C3D1
TO BE INVOICED	Serum Pregnancy test	WOCBP (on-site only)	1,000.00	13.0	13000		0.00	0.00	1,000.00	1.00
	Urine Pregnancy test	WOCBP (on-site only)	700.00	13.0	9100		0.00	0.00	700.00	1.00
	Premedication for etanercept - administration and dispensing (if oral)	Diphenhydramine and Dexamethasone	1,200.00	6.0	7200		0.00	0.00	0.00	0.00
	Premedication for etanercept - administration (if IV)	Diphenhydramine and Dexamethasone	4,997.00	6.0	29982		0.00	0.00	0.00	0.00
	Premedication for etanercept - dispensing (IV) (complex)	Diphenhydramine and Dexamethasone	2,573.00	6.0	15438		0.00	0.00	0.00	0.00
	Archival BMA sample for MRD (for cloneSEQ clonality (ID) Test)	Pre-screening	1,000.00	1.0	1000		0.00	0.00	0.00	0.00
	CMV testing	Local analysis	2,000.00	7.00	14000		0.00	1.00	2,000.00	0.00
	Per Subject Cost Subtotal			6,15,747.40		18,175.60		8,899.00		36,369.90
	Additional Cost Subtotal			89,720.00		0.00		3,700.00		0.00
	Subtotal			7,05,467.40		18,175.60		8,899.60		40,093.90
Summary Costs	Overhead			1,41,093.48		3,635.12		1,779.92		8,093.58
	INVESTIGATOR COST PER SUBJECT with Overhead			8,46,560.88		21,810.72		10,679.52		48,083.88

Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	C3D15	f	C4D1	f	C4D15
TO BE INVOICED	Serum Pregnancy test	WOCBP (on-site only)	1,000.00	13.0	13000		0.00	1.00	1,000.00	1.00
	Urine Pregnancy test	WOCBP (on-site only)	700.00	13.0	9100		0.00	1.00	700.00	1.00
	Premedication for etanercept - administration and dispensing (if oral)	Diphenhydramine and Dexamethasone	1,200.00	6.0	7200		0.00	0.00	0.00	0.00
	Premedication for etanercept - administration (if IV)	Diphenhydramine and Dexamethasone	4,997.00	6.0	29982		0.00	0.00	0.00	0.00
	Premedication for etanercept - dispensing (IV) (complex)	Diphenhydramine and Dexamethasone	2,573.00	6.0	15438		0.00	0.00	0.00	0.00
	Archival BMA sample for MRD (for cloneSEQ clonality (ID) Test)	Pre-screening	1,000.00	1.0	1000		0.00	0.00	0.00	0.00
	CMV testing	Local analysis	2,000.00	7.00	14000		0.00	1.00	2,000.00	0.00
	Per Subject Cost Subtotal			6,15,747.40		19,402.10		39,594.90		18,352.10
	Additional Cost Subtotal			89,720.00		0.00		3,700.00		0.00
	Subtotal			7,05,467.40		19,402.10		43,294.90		18,352.10
Summary Costs	Overhead			1,41,093.48		3,880.42		8,658.98		3,670.42
	INVESTIGATOR COST PER SUBJECT with Overhead			8,46,560.88		23,282.62		51,953.88		22,022.52

Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	C5D15	f	C6D1
TO BE INVOICED	Serum Pregnancy test	WOCBP (on-site only)	1,000.00	13.0	13000	1.00	1,000.00	1.00
	Urine Pregnancy test	WOCBP (on-site only)	700.00	13.0	9100	1.00	700.00	1.00
	Premedication for etanercept - administration and dispensing (if oral)	Diphenhydramine and Dexamethasone	1,200.00	6.0	7200		0.00	0.00
	Premedication for etanercept - administration (if IV)	Diphenhydramine and Dexamethasone	4,997.00	6.0	29982		0.00	0.00
	Premedication for etanercept - dispensing (IV) (complex)	Diphenhydramine and Dexamethasone	2,573.00	6.0	15438		0.00	0.00
	Archival BMA sample for MRD (for cloneSEQ clonality (ID) Test)	Pre-screening	1,000.00	1.0	1000		0.00	0.00
	CMV testing	Local analysis	2,000.00	7.00	14000	1.00	2,000.00	0.00
	Per Subject Cost Subtotal			6,15,747.40		34,459.60		18,352.10
	Additional Cost Subtotal			89,720.00		3,700.00		3,700.00
	Subtotal			7,05,467.40		38,159.60		18,352.10
Summary Costs	Overhead			1,41,093.48		7,631.92		7,631.92
	INVESTIGATOR COST PER SUBJECT with Overhead			8,46,560.88		45,791.88		22,022.52
								45,791.88



Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	C6D15	f	C7D1	f	C7D15
Additional Treatment Related Costs TO BE INVOICED	Serum Pregnancy test	WOCBP (on-site only)	1,000.00	13.0	13000	0.00	1.00	1,000.00	0.00	0.00
	Urine Pregnancy test	WOCBP (on-site only)	700.00	13.0	9100	0.00	1.00	700.00	0.00	0.00
	Premedication for ekanatalab - administration and dispensing (if oral)	Diphenhydramine and Dexamethasone	1,200.00	6.0	7200	0.00	0.00	0.00	0.00	0.00
	Premedication for ekanatalab - administration (if IV)	Diphenhydramine and Dexamethasone	4,997.00	6.0	29982	0.00	0.00	0.00	0.00	0.00
	Premedication for ekanatalab - dispensing (IV) (complex)	Diphenhydramine and Dexamethasone	2,573.00	6.0	15438	0.00	0.00	0.00	0.00	0.00
	Archival BAA sample for NRD (for cloneSEQ clarity (ID) Test)	Diphenhydramine and Dexamethasone	1,000.00	1.0	1000	0.00	0.00	0.00	0.00	0.00
	CMV testing	Pre-screening	2,000.00	7.00	14000	0.00	1.00	2,000.00	0.00	0.00
		Local analysis								
	Per Subject Cost Subtotal			6,15,747.40	18,352.10	38,054.90		12,952.10		
	Additional Cost Subtotal			89,720.00	0.00	3,700.00		0.00		
Summary Costs	Subtotal			7,05,467.40	18,352.10	41,764.90		12,952.10		
	Overhead			1,41,033.48	3,670.42	6,356.98		2,590.42		
	INVESTIGATOR COST PER SUBJECT with Overhead			8,46,560.88	22,023.52	50,153.88		15,542.62		

Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	EoT	f	F/U	f	Long Term FU Visit
Additional Treatment Related Costs TO BE INVOICED	Serum Pregnancy test	WOCBP (on-site only)	1,000.00	13.0	13000	1.00	1,000.00	1,000.00	0.00	0.00
	Urine Pregnancy test	WOCBP (on-site only)	700.00	13.0	9100	1.00	700.00	700.00	0.00	0.00
	Premedication for ekanatalab - administration and dispensing (if oral)	Diphenhydramine and Dexamethasone	1,200.00	6.0	7200	0.00	0.00	0.00	0.00	0.00
	Premedication for ekanatalab - administration (if IV)	Diphenhydramine and Dexamethasone	4,997.00	6.0	29982	0.00	0.00	0.00	0.00	0.00
	Premedication for ekanatalab - dispensing (IV) (complex)	Diphenhydramine and Dexamethasone	2,573.00	6.0	15438	0.00	0.00	0.00	0.00	0.00
	Archival BAA sample for NRD (for cloneSEQ clarity (ID) Test)	Diphenhydramine and Dexamethasone	1,000.00	1.0	1000	0.00	0.00	0.00	0.00	0.00
	CMV testing	Pre-screening	2,000.00	7.00	14000	0.00	0.00	0.00	0.00	0.00
		Local analysis								
	Per Subject Cost Subtotal			6,15,747.40	18,352.10	38,054.90		12,952.10		
	Additional Cost Subtotal			89,720.00	1,700.00	3,700.00		0.00		
Summary Costs	Subtotal			7,05,467.40	38,373.90	27,445.50		6,525.50		
	Overhead			1,41,033.48	7,674.78	5,469.10		1,305.90		
	INVESTIGATOR COST PER SUBJECT with Overhead			8,46,560.88	46,043.68	32,534.68		7,835.40		

Additional Procedures Not included in the Per Subject Cost (Procedures not tied to a specific visit)
- All Fees Inclusive of Overhead

Other Study Level Costs	Procedure	Comments	Cost
	See Arm A for Administrative Fees, Procedures applicable to all arms and patient compensation		
	Screen Fails	Applicable to subjects who SF at Visit 1. Cost reflects V1 with 25% reduction, no overhead paid. Max 5 SFs per site.	37,354.13
	Day 1: Additional Cycles (starting with C8)	Paid based on EDC data (not invoiceable). Any invoiceables from the Additional Treatment Related Costs section for Cycle 7 costs above may be invoiced additionally as incurred for the cycle (not included in amount listed here).	45,713.88
	Day 15: Additional Cycles (starting with C8)	Paid based on EDC data (not invoiceable). Any invoiceables from the Additional Treatment Related Costs section for Cycle 7 costs above may be invoiced additionally as incurred for the cycle (not included in amount listed here).	15,542.52
	Additional LTFU Visits	Paid based on EDC data, per additional LTFU visit	7,835.40
	Pre-Screening Screen Failures	To be invoiced up to total of pre-screening visit. Cap of 5 per site (additional eligible for invoice with prior Pfizer approval)	10,296.60



Attachment B
INDEMNIFICATION AND RESEARCH INJURY POLICY

Pfizer has authorized CRO to bind Pfizer to the commitments in the policy described below.

Pfizer agrees to indemnify, defend or cover costs of defense for, and hold harmless ("Indemnify") the Study investigators; any institution at which Study activities are conducted, its officers, agents, and employees; and the IRB / IEC that approved the Study (collectively, "Indemnified Parties") against any demand or claim for damages ("Claim") arising out of a Research Injury, the design of the Study, the specifications of the Study Protocol, or Pfizer's use of Study Data.

Excluded from this Agreement to Indemnify are any Claims to the extent resulting from

- (a) failure by any Indemnified Party to comply with the Protocol *
- (b) failure of any Indemnified Party to comply with any applicable law, the Rules or any governmental regulations, or
- (c) negligence or willful misconduct by any Indemnified Party.

Pfizer, through CRO, further agrees to reimburse Institution for the actual cost of diagnostic procedures and medical treatment necessary to treat a Research Injury as per the New Drugs and Clinical Trial Rules 2019. Institution agrees to directly pay the providers of all such services, whether or not the provider is affiliated with the Institution. Institution acknowledges that neither Pfizer nor CRO will directly interface with or make payments to providers or Study Subjects in connection with treatment or procedures necessary to treat a Research Injury.

Research Injury. For purposes of this Indemnification and Research Injury Policy, the term "Research Injury" means adverse event, physical injury, or illness caused by treatment or procedures required by the Protocol that the Study Subject would not have received if the Study Subject had not participated in the Study. Principal Investigator and Institution agree to provide or arrange for prompt diagnosis and medical treatment of any Research Injury experienced by a Study Subject. Principal Investigator further agrees to promptly notify CRO of any Research Injury.

Notice and Cooperation. Principal Investigator and Institution agree to provide CRO with prompt notice of, and Pfizer with full cooperation in handling and resolving, any Claim that is subject to Indemnification. However, failure to provide timely notice will not relieve Pfizer of its obligation to Indemnify except to the extent that Pfizer is prejudiced by the delay. Such cooperation will include assisting Pfizer in the management of a Claim until it is fully resolved, which may entail Pfizer requesting and reviewing medical bills and records related to a Research Injury. If so requested by Pfizer, Principal Investigator and Institution agree to authorize Pfizer to carry out the sole management of defense of an Indemnified Claim.

* Slight deviations that do not contribute to the injury or jeopardize the validity of the Study will not be considered a failure to adhere to the Protocol.



Settlement or Compromise. No settlement or compromise of a Claim subject to Indemnification will be binding on Pfizer without Pfizer's prior written consent. Pfizer will not unreasonably withhold such consent of a settlement or compromise. No party will admit fault on behalf of any other party or enter into a non-monetary settlement that places future obligations on another party without the written approval of the affected party.



Attachment C
EQUIPMENT AND MATERIALS

CRO/Pfizer-Provided Equipment and Materials

CRO/Pfizer-Provided Equipment

CRO or Pfizer will provide the equipment identified below (“**CRO Equipment**”) for use by Principal Investigator or Institution in the conduct or reporting of the Study: NONE

CRO/Pfizer-Provided Materials

CRO or Pfizer will provide the proprietary materials owned or licensed by CRO or Pfizer and identified below (“**CRO Materials**”) for use by Principal Investigator or Institution in the conduct or reporting of the Study.

Materials Supplied: NONE

Vendor-Provided Equipment or Materials

CRO or Pfizer will arrange for a vendor to provide the following equipment or proprietary materials (“**Vendor Property**”) for use in this Study:

TrialMax Slate® Bluebird Smart Tablet Computer (Global) Model name: ST102-W4LAL (Global) Bluebird Inc

Permitted Uses of Vendor Property

Principal Investigator and Institution will use Vendor Property only for purposes of this Study.

Disposition of Vendor Property

The vendor will determine the disposition of Vendor Property after completion of Study conduct.

Ownership, Responsibilities, and Liability

Ownership. CRO Equipment, CRO Materials, and Vendor Property are and remain the property of CRO, Pfizer, the vendor, or the licensor, as the case may be.

Responsibilities. The party receiving and using them will bear the risk of loss or damage to CRO Equipment, CRO Materials, and Vendor Property. If any CRO Equipment, CRO Materials, or Vendor Property must be replaced by CRO, Pfizer or vendor during Study conduct as the result of loss or damage by a party to this Agreement, CRO reserves the right to deduct, from future Study funding payments, the cost to CRO or Pfizer of the replacements.



Liability. Neither CRO nor Pfizer has any liability for damages of any sort, including personal injury or property damage, resulting from the use of CRO Equipment, CRO Materials, or Vendor Property except to the extent that (1) such damages were caused by the negligence or willful misconduct of CRO, Pfizer, or the vendor or (2) a personal injury constitutes a Research Injury to a Study Subject, as described in Attachment B to this Agreement.



Attachment D
PFIZER INTERNATIONAL ANTI-BRIBERY AND
ANTI-CORRUPTION BUSINESS PRINCIPLES

Pfizer has a long-standing policy forbidding bribery and corruption in the conduct of our business in the United States or abroad. Pfizer is committed to performing business with integrity, and acting ethically and legally in accordance with all applicable laws and regulations. We expect the same commitment from the consultants, agents, representatives or other companies and individuals acting on our behalf ("Business Associates"), as well as those acting on behalf of Business Associates (e.g., subcontractors), in connection with work for Pfizer.

Bribery of Government Officials

Most countries have laws that forbid making, offering or promising any payment or anything of value (directly or indirectly) to a Government Official when the payment is intended to influence an official act or decision to award or retain business.

"Government Official" shall be broadly interpreted and means:

- (i) any elected or appointed Government official (e.g., a legislator or a member of a Government ministry);
- (ii) any employee or individual acting for or on behalf of a Government Official, agency, or enterprise performing a governmental function, or owned or controlled by, a Government (e.g., a healthcare professional employed by a Government hospital or researcher employed by a Government university);
- (iii) any political party officer, candidate for public office, officer, or employee or individual acting for or on behalf of a political party or candidate for public office;
- (iv) any employee or individual acting for or on behalf of a public international organization;
- (v) any member of a royal family or member of the military; and
- (vi) any individual otherwise categorized as a Government Official under law.

"Government" means all levels and subdivisions of governments (i.e., local, regional, or national and administrative, legislative, or executive).

Because this definition of "Government Official" is so broad, it is likely that Business Associates will interact with a Government Official in the ordinary course of their business on behalf of Pfizer. For example, doctors employed by Government-owned hospitals would be considered "Government Officials."

The U.S. Foreign Corrupt Practices Act (the "FCPA") prohibits making, promising, or authorizing a payment or providing anything of value to a non-U.S. Government Official to improperly or corruptly influence that official to perform any governmental act or make a decision to assist a company in obtaining or retaining business, or to otherwise gain an improper advantage. The FCPA also prohibits a company or person from using another company or individual to engage in any such activities. As a U.S. company, Pfizer must comply



with the FCPA and could be held liable as a result of acts committed anywhere in the world by a Business Associate.

Anti-Bribery and Anti-Corruption Principles Governing Interactions with Governments and Government Officials

Business Associates must communicate and abide by the following principles with regard to their interactions with Governments and Government Officials:

- Business Associates, and those acting on their behalf in connection with work for Pfizer, may not directly or indirectly make, promise, or authorize the making of a corrupt payment or provide anything of value to any Government Official to induce that Government Official to perform any governmental act or make a decision to help Pfizer obtain or retain business. Business Associates, and those acting on their behalf in connection with work for Pfizer, may never make a payment or offer any item or benefit to a Government Official, regardless of value, as an improper incentive for such Government Official to approve, reimburse, prescribe, or purchase a Pfizer product, to influence the outcome of a clinical trial, or to otherwise benefit Pfizer's business activities improperly.
- In conducting their Pfizer-related activities, Business Associates, and those acting on their behalf in connection with work for Pfizer, must understand and comply with any local laws, regulations, or operating procedures (including requirements of Government entities such as Government-owned hospitals or research institutions) that impose limits, restrictions, or disclosure obligations on compensation, financial support, donations, or gifts that may be provided to Government Officials. If a Business Associate is uncertain as to the meaning or applicability of any identified limits, restrictions, or disclosure requirements with respect to interactions with Government Officials, that Business Associate should consult with his or her primary Pfizer contact before engaging in such interactions.
- Business Associates, and those acting on their behalf in connection with work for Pfizer, are not permitted to offer facilitation payments. A "facilitation payment" is a nominal payment to a Government Official for the purpose of securing or expediting the performance of a routine, non-discretionary governmental action. Examples of facilitation payments include payments to expedite the processing of licenses, permits or visas for which all paperwork is in order. In the event that a Business Associate, or someone acting on their behalf in connection with work for Pfizer, receives or becomes aware of a request or demand for a facilitation payment or bribe in connection with work for Pfizer, the Business Associate shall report such request or demand promptly to his or her primary Pfizer contact before taking any further action.

Commercial Bribery

Bribery and corruption can also occur in non-Government, business to business relationships. Most countries have laws which prohibit offering, promising, giving, requesting, receiving, accepting, or agreeing to accept money or anything of value in exchange for an improper business advantage. Examples of prohibited conduct could include, but are not limited to, providing expensive gifts, lavish hospitality, kickbacks, or investment opportunities in order to improperly induce the purchase of goods or services. Pfizer colleagues are not permitted to offer, give, solicit or accept bribes, and we expect our Business Associates, and those acting on their behalf in connection with work for Pfizer, to abide by the same principles.



Anti-Bribery and Anti-Corruption Principles Governing Interactions with Private Parties and Pfizer Colleagues

Business Associates must communicate and abide by the following principles with regard to their interactions with private parties and Pfizer colleagues:

- Business Associates, and those acting on their behalf in connection with work for Pfizer, may not directly or indirectly make, promise, or authorize a corrupt payment or provide anything of value to any person to influence that person to provide an unlawful business advantage for Pfizer.
- Business Associates, and those acting on their behalf in connection with work for Pfizer, may not directly or indirectly, solicit, agree to accept, or receive a payment or anything of value as an improper incentive in connection with their business activities performed for Pfizer.
- Pfizer colleagues are not permitted to receive gifts, services, perks, entertainment, or other items of more than token or nominal monetary value from Business Associates, and those acting on their behalf in connection with work for Pfizer. Moreover, gifts of nominal value are only permitted if they are received on an infrequent basis and only at appropriate gift-giving occasions.

Reporting Suspected or Actual Violations

Business Associates, and those acting on their behalf in connection with work for Pfizer, are expected to raise concerns related to potential violations of these International Anti-Bribery and Anti-Corruption Principles or the law. Such reports can be made to a Business Associate's primary point of contact at Pfizer, or if a Business Associate prefers, to Pfizer's Compliance Group by e-mail at corporate.compliance@pfizer.com or by phone at 1-212-733-3026.



Certificate Of Completion

Envelope Id: C74AAF26603A4D6E99A348AAE355F632
 Subject: DocuSign: 263708 C1071007 IND 1284 CSA Verma English 20230411 1.0.pdf
 Source Envelope:
 Document Pages: 77
 Certificate Pages: 5
 AutoNav: Enabled
 Envelope Stamping: Enabled
 Time Zone: (UTC-08:00) Pacific Time (US & Canada)

Status: Completed

Envelope Originator:
 Susan Liu
 8 Federal Street
 Billerica, MA 01821
 Susan.Liu@parexel.com
 IP Address: 124.219.44.195

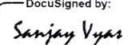
Record Tracking

Status: Original 4/20/2023 3:16:54 AM	Holder: Susan Liu Susan.Liu@parexel.com	Location: DocuSign
Status: Original 4/20/2023 3:23:00 AM	Holder: DocuSign SSU shared account DocuSign.SSU@parexel.com	Location: DocuSign

Signer Events

Sanjay Vyas
 Sanjay.Vyas@parexel.com
 EVP, India Country Head & MD
 Parexel International
 Security Level: Email, Account Authentication
 (Required)

Signature

DocuSigned by:

 CA8FD795E39E490...

Signature Adoption: Pre-selected Style
 Using IP Address: 14.142.50.74

Timestamp

Sent: 4/20/2023 3:22:59 AM
 Viewed: 4/20/2023 3:29:18 AM
 Signed: 4/20/2023 3:29:35 AM

Electronic Record and Signature Disclosure:

Accepted: 6/16/2021 6:52:18 AM
 ID: 1f415ae6-4773-46f6-8298-bb9fec647ae1

In Person Signer Events**Signature****Timestamp****Editor Delivery Events****Status****Timestamp****Agent Delivery Events****Status****Timestamp****Intermediary Delivery Events****Status****Timestamp****Certified Delivery Events****Status****Timestamp****Carbon Copy Events****Status****Timestamp**

Jhalak Jerajani
 Jhalak.Jerajani@parexel.com

Security Level: Email, Account Authentication
 (Required)

COPIED

Sent: 4/20/2023 3:22:59 AM
 Viewed: 4/20/2023 3:35:18 AM

Electronic Record and Signature Disclosure:

Accepted: 2/28/2023 10:19:09 PM
 ID: 7a3b74b9-dd06-4e05-b90f-91f1bafe07f9

Marina, Julian

Julian.Marina@PAREXEL.com

Security Level: Email, Account Authentication
 (Required)

COPIED

Sent: 4/20/2023 3:23:00 AM

Electronic Record and Signature Disclosure:

Not Offered via DocuSign

Witness Events**Signature****Timestamp**

Notary Events	Signature	Timestamp
Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	4/20/2023 3:23:00 AM
Certified Delivered	Security Checked	4/20/2023 3:29:18 AM
Signing Complete	Security Checked	4/20/2023 3:29:35 AM
Completed	Security Checked	4/20/2023 3:29:35 AM
Payment Events	Status	Timestamps
Electronic Record and Signature Disclosure		



ELECTRONIC RECORD AND SIGNATURE DISCLOSURE

From time to time, Parexel (we, us or Company) shall provide certain written notices or disclosures through electronic mail including but not limited to any disclosures required by law. Described below are the terms and conditions which we will provide to you for such notices and disclosures electronically through the DocuSign system.

Please read the information below carefully and thoroughly, and if you agree and consent to this Electronic Record and Signature Disclosure ("ERSD") procedure, please confirm your agreement and consent by selecting the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

Definitions:

"DocuSign" means the intranet system portal for you to access and receive Electronic Records and provide Electronic Signatures.

"Electronic Record" means a record created, generated, sent, communicated, received or stored by electronic means.

"Electronic Signature" means a computer data compilation of any symbol or series of symbols executed, adopted or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

We and you agree to comply with all applicable laws related to this ERSD form, including but not limited to any applicable data privacy laws.

Getting paper copies

At any time, you will have the ability to download and print documents we send to you through the DocuSign system during and immediately after the signing session and, if you elect to create a DocuSign account, you may also access the documents for a limited period of time (30 days) after such documents are first sent to you. After such time you will not be able to access the documents.

All notices and disclosures will be sent to you electronically

We will provide electronically to you through the DocuSign system all required notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you during the course of our relationship with you. To reduce the chance of you inadvertently not receiving any notice or disclosure, we prefer to provide all of the required notices and disclosures to you by the same method and to the same address that you have given us.

Confidentiality



Any and all Electronic Records are private and confidential and must be kept strictly confidential at all times. Any and all Electronic Records shall belong to Parexel and/or its client, as applicable.

How to contact Parexel:

You may contact us to let us know of your changes as to how we may contact you electronically, and to withdraw your prior consent to receive notices and disclosures electronically as follows: globalsiteagreementsignatures@parexel.com

To advise Parexel of your new email address

You must let us know immediately of a change in your email address where we should send notices and disclosures electronically to you, you must send an email message to us at globalsiteagreementsignatures@parexel.com and in the body of such request you must state: your previous email address, your new email address. We do not require any other information from you to change your email address.

Required hardware and software

The minimum system requirements for using the DocuSign system may change over time. The current system requirements are found here: <https://support.docusign.com/guides/signer-guide-signing-system-requirements>.

Acknowledging your access and consent to receive and sign documents electronically

To confirm to us that you can access this information electronically, which will be similar to other electronic notices and disclosures that we will provide to you, please confirm that you have read this ERSD, and (i) that you are able to print on paper or electronically save this ERSD for your future reference and access; or (ii) that you are able to email this ERSD to an email address where you will be able to print on paper or save it for your future reference and access. Further, if you consent to receiving notices and disclosures exclusively in electronic format as described herein, then select the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

By selecting the check-box next to 'I agree to use electronic records and signatures', you confirm that:

- You can access and read this Electronic Record and Signature Disclosure; and
- You can print on paper this Electronic Record and Signature Disclosure, or save or send this Electronic Record and Disclosure to a location where you can print it, for future reference and access; and



- Until or unless you notify Parexel as described above, you consent to receive exclusively through electronic means all notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you by Parexel during the course of your relationship with Parexel.

