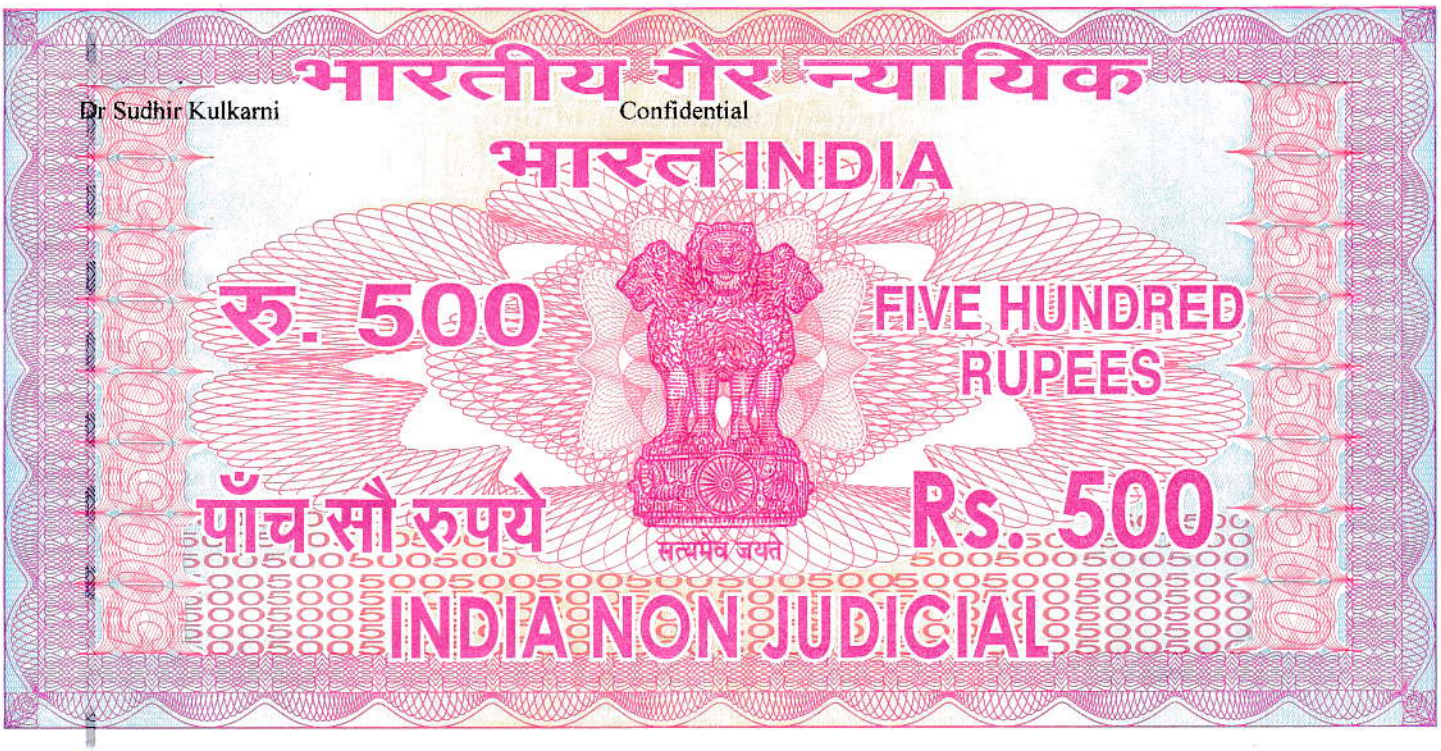

महाराष्ट्र MAHARASHTRA ◐ 2016 ◐ AC 366625

मुद्रांक विक्री नोंदवही अनु. क्रमांक 2442 दिनांक 19 MAY 2017
दस्ताचा प्रकार- Consent Agreement मुद्रांक शुल्क रक्कम 500 = -
दस्त नोंदणी करणार आहेत का? होय(Yes)/ नाही(No)
मिळकतीचे थोडक्यात वर्णन-
मुद्रांक विकत घेणाऱ्याचे नांव Lupin Ltd - Nande Mulashi Pune
दुसऱ्या पक्षकारांचे नांव Dr. Sudhir Kulkarni - MGM IMCEC - Aurangabad.
हस्ते असल्यास त्यांचे नांव Parmod Kulkarni - Vidyanagar Pune

19 MAY 2017

रविंद्र वा. मिरजकर
ला. नं. HVL VIII-2201096
शिवाजीनगर, पुणे- 32.
मुद्रांक विकत घेणारे/ हस्ते व्यक्तिची सही

ज्या कारणासाठी ज्यांनी मुद्रांक खरेदी केला त्यांनी त्याच कारणासाठी मुद्रांक खरेदी केल्यापासून ६ महिन्यात वापरणे बंधनकारक आहे.

CLINICAL TRIAL AGREEMENT
Protocol # LRP/LNP1892/2016/007

This Clinical Trial Agreement ("Agreement") is made as on 14th August, 2017 between

Lupin Limited, incorporated under the laws of India with its registered office located at 3rd Floor, Kalpataru Inspire, Off Western Express Highway, Santacruz East, Mumbai 400055 and having PAN: AAACL1069K, including its successors, assigns and Affiliates (hereinafter "**Lupin**");

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and

Dr Sudhir Kulkarni, an Indian citizen/ resident, with his address at Advet, 113, Samarth Kidney and Hypertension Clinic, Tilak Nagar, Aurangabad 431001 and having PAN: ABPPK6988B (hereinafter "**Principal Investigator**");

and

Mahatma Gandhi Mission Medical College and Hospital, with its address at N-6, CIDCO, Aurangabad 431003 (hereinafter "**Institution**")

and

Grapecity Research Solutions LLP, limited liability partnership having its registered address at Block No. D/2, Prakash Hsg. Society, Near Kalewadi Fata, Thergaon, Pune 411033 and having PAN: AAPFG8186L (hereinafter "**SMO**").

Lupin wishes to support a clinical trial entitled Protocol # LRP/LNP1892/2016/007 "A Randomized, Double – Blind, Placebo – Controlled, Phase 2 Study to Assess the Efficacy, Pharmacokinetics, Pharmacodynamics and Safety of LNP1892 (Monotherapy) in Chronic Kidney Disease (CKD) Patients with Secondary Hyperparathyroidism (SHPT), On Dialysis and Not on Dialysis" ("**Protocol**") to be conducted at Institution and to involve Trial Subjects (collectively, "**Trial**" or "**Study**").

The parties agree as follows:

1. Definitions:

1.1 **Affiliate**: means with respect to a Person, any other Person which, directly or indirectly through one or more intermediaries, Controls, is Controlled by or is under common Control with the first mentioned Person, "Control" shall mean with respect to any Party, the possession, directly or indirectly, of 50% or more of the voting securities and/ or the power to direct or cause the direction of the board and/ or management and/or policies of that Person, whether through ownership of voting securities, contract or otherwise.

1.2 **Applicable Laws**: means any statute, law, regulation, ordinance, rule, judgment, injunction, order, decree, ruling, license, permit, consent, approval, directive, agreement, guideline, policy or restriction, or any requirement or decision or interpretative, legislative or administrative action of, or determination by, any Authority having jurisdiction over the matter in question, or otherwise applicable to the Parties, whether in effect as of the date of this Agreement or at any time thereafter; and including all data protection, privacy, drug, anti-competitive, anti-corruption, anti-bribery as well as export and re-export laws and regulations, GCP and related United States Food and Drug Administration ("FDA"), European Medicines Agency ("EMA") and India Food and Drugs Administration (or any other similar Authority), regulations and guidelines.

1.3 **Authority**: means any constitutional, judicial, governmental, quasi-governmental, legislative, statutory, quasi-judicial, departmental, regulatory or public body constituted by any statute or ordinance or by a court of competent jurisdiction, or any authority having jurisdiction over the Parties or the subject matter of this Agreement.

1.4 **Intellectual Property Rights**: includes patents, trademarks, service marks, logos, trade names, internet domain names, copyright and moral rights, database rights, semi-conductor topography

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rights, rights in designs, rights in inventions, rights in know-how and other intellectual property rights, in each case whether registered or unregistered, and all rights or forms of protection having equivalent or similar effect anywhere in the world and the term 'registered' includes registrations and applications for registration, rights to Study Results, economic copyrights and know-how therein conceived, generated or reduced to practice during the Study.

1.5 **Invention**: shall be understood in the widest sense of the word, in particular including but not limited to patentable and non-patentable technical inventions, discoveries, improvements, and innovations of any kind.

1.6 **Party:** means Lupin, Institution, Principal Investigator and SMO and "Parties" shall mean all of them.

1.7 **Person**: means any individual, corporation, company, partnership, trust, limited liability company, association or other entity.

1.8 **Study Site:** means the premises on which the Study will be carried out.

1.9 **Study:** means the investigation to be conducted at the Study Site in accordance with the Protocol.

1.10 **Study Team:** means the Principal Investigator, Sub-Investigator(s), Institution staff, employees of Institution's Affiliates or any person involved in the conduct of the Study at the Study Site.

1.11 **Regulatory Approval**: mean any and all permits, consents, grants, approvals, authorizations, licenses, waivers, exemptions, concessions, sanctions, permissions, registrations, certificates, agreements, orders, declarations, filings, reports or notices of, with or to any Authority pursuant to Applicable Law.

1.12 **Research Staff:** Institution staff, employees of Institution's Affiliates or any person involved in the conduct of the Study at the Study Site.

2. Investigators and Research Staff.

2.1 Principal Investigator. The Principal Investigator is an employee of the Institution who will be responsible for the direction of the Trial in accordance with applicable Institution policies. The Principal Investigator commits himself and his Research Staff to conduct the Trial as per the Protocol and the Applicable Laws, against fair compensation.

2.2 Sub-investigators and Research Staff. Principal Investigator will ensure that only individuals who are appropriately trained and qualified assist in the conduct of the Trial as Sub-investigators or Research Staff.

2.3 Obligations of Principal Investigator. Principal Investigator shall be solely responsible for strict compliance by all Trial personnel, including the Sub-investigators and the Research Staff, with the terms of this Agreement. Principal Investigator shall ensure that any personnel who assist in the conduct of the Trial are informed of and agree to abide by all terms of this Agreement applicable to the activities they perform. Principal Investigator will assume all those responsibilities assigned to all principal investigators under various Applicable Laws, rules, regulations, guidelines and standards including without limitation all relevant International Conference on Harmonization Good Clinical Practice ("ICH GCP") guidelines and standards, and all Applicable Laws including those relating to the confidentiality, privacy and security of patient information.

2.4 The Principal Investigator shall be solely responsible and liable for performance of the obligations under this Agreement by the Study Team. Any breach committed by the Sub-investigator or any other member of the Study Team shall be deemed to be a breach committed by the Principal Investigator. Nothing contained herein shall discharge or relieve Principal Investigator from its obligations or liability hereunder.

2.5 No Substitution. Principal Investigator may not reassign the conduct of the Trial to a different principal investigator without prior written authorization from Lupin. In the event Lupin approves such replacement, such replacement principal investigator will be required to agree to the terms and conditions of this Agreement separately in writing. In the event Lupin does not approve a replacement principal investigator, Lupin will have the option to terminate this Agreement in accordance with the termination provisions below.

2.6 Delegation of duties by Principal Investigator. Principal Investigator may delegate duties and responsibilities to Sub-investigators or Research Staff only to the extent permitted by Applicable Law governing the Trial Conduct, as described below.

2.7 Compliance with Institutional Policies. Principal Investigator will comply with the policies and procedures of the Institution, with which Principal Investigator is affiliated, including any applicable financial policies. Principal Investigator will notify Lupin promptly of any conflict between the terms of this Agreement and any such policy or procedure, and the Parties will attempt to reach an appropriate accommodation.

3. Protocol. The Principal Investigator shall conduct the Trial in accordance with the Protocol.

3.1 Amendments. The Protocol may be modified only by a written Amendment, signed by both, Lupin and the Principal Investigator. The parties acknowledge that Protocol Amendments are also subject to approval by the responsible Institutional Ethics Committee ("IEC").

3.2 Emergency Amendments. If it is necessary to change the Protocol on an emergency basis for the safety of the Trial Subjects (hereinafter defined), Principal Investigator will notify Lupin and the responsible IEC as soon as practicable but, in any event, no later than three working days after the change is implemented. Any emergency change to the Protocol must be followed by a written Amendment duly executed by Lupin and the Principal Investigator.

3.3 No Additional Research. Principal Investigator represents and warrants that no additional research will be conducted on Trial Subjects during the conduct of the Trial, unless it is approved by Lupin in writing, and documented as a companion protocol or an Amendment to the original Protocol. Such prohibited research activities include analyses of biological samples from Trial Subjects for any non-therapeutic purpose.

4. Institutional Ethics Committee. Before the Trial is initiated, Principal Investigator will ensure that both the Trial and the informed consent form are approved by an IEC that complies with all applicable regulations. Principal Investigator will further ensure that the Trial is subject to continuing oversight by the IEC throughout its conduct.

4.1 Trial Disapproval. If, through no fault of Principal Investigator, the Trial is disapproved by the IEC, this Agreement will immediately terminate with no penalty to the Principal Investigator, as outlined below.

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5. Trial Conduct. Principal Investigator will conduct the Trial in accordance with the Protocol, Lupin's or its designee's written instructions and Applicable Law.

5.1 Trial Initiation: Prior to initiation of the Trial, Lupin shall organize an investigator meeting for all investigators who are taking part in the clinical trial for Lupin Drug, at such place and time as finalized by Lupin ("**Investigator Meeting**"). The purpose of the Investigator Meeting will including but not limited to, to make the investigators aware about – (i) scientific aspect of the clinical trial; (ii) standard operating procedures including documentation process and adverse event reporting; (iii) Protocol and various regulatory guidelines within which the investigator needs to conduct clinical trial for Lupin Drug. The Principal Investigator agrees to attend the said Investigator Meeting along with such members of its Research Staff, as approved by Lupin ("**Attendees**"). Lupin agrees that it shall arrange for the travel and boarding and lodging of the Investigator Meeting Attendees.

6. Lupin Drug. Lupin will provide the Principal Investigator with sufficient quantities of Lupin product that is being studied ("**Lupin Drug**") to conduct the Trial. If required by the Protocol and unless otherwise agreed in writing, Lupin will also provide placebo or comparator drug ("**Comparator Drug**").

6.1 Custody and Dispensing. Principal Investigator will adhere to Applicable Law and industry standards requiring careful custody and dispensing of Lupin Drug or Comparator Drug, as well as appropriate documentation of such activities.

6.2 Control. Principal Investigator will maintain appropriate control of supplies of Lupin Drug or Comparator Drug and will not administer or dispense it to anyone who is not a Trial Subject, or provide access to it to anyone except Principal Investigator, Sub-investigators, or Research Staff.

6.3 Use. Principal Investigator will use Lupin Drug or Comparator Drug only as specified in the Protocol. Any other use of Lupin Drug or Comparator Drug constitutes a material breach of this Agreement.

6.4 Ownership of Lupin Drug. Lupin Drug is and remains the sole and exclusive property of Lupin. Lupin grants or assigns Principal Investigator no express or implied intellectual property rights in Lupin Drug or in any methods of making or using Lupin Drug.

6.5 Payment for Lupin Drug or Comparator Drug. Principal Investigator will not charge a Trial Subject or third-party payer for Lupin Drug or Comparator Drug or for any services reimbursed by Lupin under this Agreement.

7. **Representation and Warranties**:

7.1 The Principal Investigator and Institution hereby jointly and severally represent and warrant to Lupin the following:

a. The Principal Investigator is trained and qualified to conduct clinical trials at the Study Site, and the Study Team working on the Study shall be appropriately trained in ICH GCP and the Protocol;

b. The Principal Investigator and the Study Team shall perform the Study in an efficient and professional manner and shall complete the Study within the time period as informed by Lupin from time to time;

c. The Principal Investigator and Institution shall duly observe and follow all directives, conditions and restrictions, if any imposed by the respective Authority(ies) under the applicable Regulatory Approval. It shall not in any during the course of its business with any other party, breach directly or indirectly, any Applicable Law which may have an impact on the Study in any manner;

d. The Principal Investigator and the Study Team shall conduct the Study under the review and direct supervision of Lupin, the EC, or an appropriate independent review committee of scientists or other qualified individuals or any such board, body or committee authorized to co-ordinate, review and safeguard the rights, safety and well-being of the Trial Subject;

e. The representation, warranties set out hereunder may be relied upon in any applications to any Authority(ies);

f. The Principal Investigator and/or the Institution shall not, at all times during the term hereof, neither appoint nor utilize the services nor assign the activities of the Study contemplated under the Protocol to any Sub-investigator(s), who is debarred under any regulatory requirements/ Laws or statutes from undertaking or performing the Study or the obligations hereunder;

g. The Principal Investigator shall ensure the safe custody of the Study Drug in accordance with the Protocol and shall not use the Study Drug for any purpose other than the purpose of this Agreement;

h. The Principal Investigator and/or the Institution shall publish any data in connection with the Study only in accordance with the Protocol;

i. The Principal Investigator and the Institution shall promptly notify Lupin in writing of any change in the truth of any of the aforesaid representations;

j. The Principal Investigator shall take necessary and appropriate steps to inform its Study Team of the terms and conditions of this Agreement and to ensure that such persons comply with the terms and conditions of this Agreement;

k. The Principal Investigator and the Institution shall at all times be accountable to Lupin for any and all breach, action, inaction or omission, committed by the Study Team, support staff and personnel provided by it for conducting the Study;

l. In the event the Study Site is inspected and the Study data are audited / examined by any Authority(ies) having competent jurisdiction under the regulatory requirements or Applicable Laws, the Principal Investigator and/or the Institution shall forthwith notify Lupin in writing of such inspection, inquiry, audit or examination conducted by such Authority(ies);

m. The Principal Investigator shall co-ordinate, co-operate with and assist in conducting the Study and shall perform such obligations and duties, as may be assigned or imposed upon him/her, in a timely manner, in accordance with the regulatory requirements and Applicable Law;

n. The Principal Investigator and/or the Institution shall not in any during the course of its

business with any other party, breach directly or indirectly, any Applicable Law which may have an impact on the Study / Study Agreement in any manner;

o. The Principal Investigator and the Institution shall apply for, and obtain, maintain, renew all the applicable approvals including Regulatory Approvals, if any, during the term of the Agreement. Further, the Principal Investigator and the Institution shall during the term of this Agreement abide by all Applicable Laws, as amended from time to time;

p. The Principal Investigator and the Institution shall perform such other roles, responsibilities and duties related to the Trial, as may be reasonably required by Lupin from time to time; and

q. The Principal Investigator shall maintain true and complete financial records relating to the Study performed under this Agreement including costs and expenses incurred in connection with the Study.

7.2 Each Party hereby represents, warrants and undertakes as follows:

a. it has taken all necessary action on its part required to authorize the execution and delivery of this Agreement;

b. this Agreement constitutes a legal, valid and binding obligation of the Parties; and

c. neither the execution nor the delivery of this Agreement nor its performance would violate any agreement nor constitute a default under any such agreements to which the Parties are a party.

7.3 Lupin hereby represents and warrants to the Institution that it will, during the term of this Agreement abide by all Applicable Laws including provisions of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945, as amended from time to time.

8. Intellectual Property Rights

8.1 The Principal Investigator and/or the Institution shall duly notify Lupin, in a confidential written notification, of any Invention and/or Intellectual Property Rights arising as an incident to and/or during the conduct of the Study.

8.2 Principal Investigator and the Institution acknowledge and agree that any Intellectual Property Rights relating to the Study shall be deemed to be works for hire created for Lupin, who shall claim such Intellectual Property Rights through Lupin and shall hold sole title to such Intellectual Property Rights. All such Intellectual Property Rights shall be deemed assigned to Lupin, and the Principal Investigator and the Institution shall do or cause to be done all such things and deliver or cause to be delivered all such documents as are necessary to give effect to this provision The Principal Investigator shall ensure that all members of the Study Team assign all Intellectual Property Rights to Lupin.

8.3 Principal Investigator and the Institution hereby jointly undertake that:

a. The Principal Investigator will unequivocally transfer to Lupin the right to obtain patent on Invention.

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b. Principal Investigator shall take all steps necessary to secure Inventions and Intellectual Property Rights for the benefit of Lupin. To ensure the duties set forth in this Section are carried out, Lupin may, at its own cost, request that Principal Investigator prepares and signs appropriate documents and authorisations, as well as performs any other actions necessary for the rights to Inventions and Intellectual Property Rights to be vested fully and effectively in Lupin. Lupin has the exclusive right to choose the form of protection of intellectual property.

c. Principal Investigator shall refrain from taking any actions that would prejudice the Intellectual Property Rights of Lupin in any way. Moreover, Principal Investigator agrees to inform Lupin of any known infringement of its Intellectual Property Rights, and to support Lupin, at Lupin's expense, in actions intended to protect Lupin's Intellectual Property Rights.

d. Lupin shall have exclusive and undisputed ownership of anything related to the Study, including without limitation, the Confidential Information, the Study Drug, the CRFs, the Protocol and the Study Results.

8.4 Any and all Intellectual Property Rights in relation to the foregoing in Section 8.3(d) shall vest exclusively in Lupin.

8.5 The provisions of this Section shall survive the expiration and/or termination of this Agreement indefinitely.

9. Research Grant. Funding will be made to the SMO on behalf of the Principal Investigator, by way of grant payments in accordance with Attachment-B. The grant represents Principal Investigator's costs of conducting the Trial. All amounts are inclusive of all direct, indirect, overhead and other costs, including laboratory and ancillary service charges, and will remain firm for the duration of the Trial, unless otherwise agreed in writing by the parties. The Principal Investigator will not directly or indirectly seek or receive compensation from patient(s) participating in the Trial ("Trial Subject(s)") or third-party payers for any material, treatment or service that is required by the Protocol and provided or paid by Lupin, including, but not limited to, Lupin Drug, Comparator Drug, Trial Subject screening, infusions, physician and nurse services, diagnostic tests, and Lupin Drug and/or Comparator Drug administration.

Principal Investigator and the Institution hereby agree that Lupin can make all payments to the SMO on their behalf and that the Principal Investigator and/or the Institution do not have any objection to the same.

It is the responsibility of the SMO, institution and the Principal Investigator to sort out any payment related disputes amongst themselves and Lupin shall not be responsible in any manner whatsoever for the same. The SMO, Principal Investigator and the Institution hereby jointly and severally indeminfy Lupin from any loss that Lupin may suffer as a result of such dispute affecting the Trial in any manner.

10. Trial Subject Enrollment. Principal Investigator has agreed to enroll Trial Subjects in the Trial in accordance with the Protocol. Lupin reserves the right, on written notice, to limit the number of Subjects to be included in the Study, including, but not limited to instances where the recruitment target has been reached.

10.1 Multi-Center Studies. Lupin may discontinue patient enrollment if the total enrollment needed for a multi-center Trial has been achieved.

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11. Informed Consent. Principal Investigator undertakes that it will obtain a written Informed Consent Form ("**ICF**") for each Trial Subject explaining the Trial Subject's rights in connection with its relationship with the Institution and Principal Investigator. Principal Investigator will maintain a signed original of that ICF in the Trial Subject's record. Principal Investigator will provide Lupin an opportunity to review and approve the content of the ICF, including any revisions made during the course of the Trial, before it is used. Principal Investigator will allow Lupin or its designee to inspect signed ICFs or photocopies thereof during monitoring visits or audits. Principal Investigator will submit any modifications it may propose to the ICF to Lupin for review and written approval by Lupin before submitting the ICF for IEC approval. The Principal Investigator will ensure that every Trial Subject signs an ICF approved by Lupin and the IEC before the Trial Subject begins participating in the Trial. When required, the approved ICF will be modified to reflect amendments to the Protocol.

12. Adverse Events. Principal Investigator will report adverse events experienced by Trial Subjects in accordance with instructions in the Protocol and applicable regulations. This includes, where required, prompt reporting by telephone. If a Trial Subject is physically injured by Lupin Drug or properly performed Trial procedures and the Institution, Principal Investigator and other individuals participating in the conduct of the Trial have followed the Protocol, all Applicable Laws and regulations and all directions of Lupin, Lupin will reimburse the reasonable costs of medical expenses necessary to treat the injury.

13. Protected Health Information. The Parties recognize a common goal of securing all individually identifiable health information and holding such information in confidence and protecting it from unauthorized disclosure. Principal Investigator represents and warrants that he/she will comply with the provisions of any Applicable Laws relating to the confidentiality, privacy and security of such information.

13.1 Authorization to Use and Disclose Health Information. Principal Investigator will obtain a written privacy authorization, complying with Applicable Law, for each Trial Subject which will enable Principal Investigator to provide Lupin and other persons and entities designated by Lupin with completed Case Report Forms ("**CRFs**"), source documents and all other information required by the Protocol. Lupin, though not a covered entity, recognizes that, pursuant to this Agreement, it has the responsibility to protect all individually identifiable patient information and to restrict the use of such information to those persons and entities, including consultants, contractors, subcontractors and agents, who must have access to such information in order to fulfill their assigned duties with respect to the Trial. Such use also will be restricted to those uses permitted in the authorization forms and neither Lupin nor any party to whom Lupin may disclose individually identifiable health information may use such information to recruit research subjects to additional studies, to advertise additional studies or products, or to perform marketing or marketing research. Principal Investigator will provide Lupin an opportunity to review and approve the content of the authorization (including any revisions made during the course of the Trial) before it is used.

14. Confidential Information. During the course of the Trial, Principal Investigator and/or the Institution may receive or generate information that is confidential to Lupin Affiliate.

14.1 Definition. Except as specified below, Confidential Information includes all information provided by Lupin, or developed for Lupin, Inventions (hereinafter defined), and all data collected during the Trial, including without limitation results, reports, technical and economic information, the existence or terms of this or other Trial agreements with Lupin, commercialization and Trial strategies, trade secrets and know-how disclosed by Lupin to Principal Investigator and/or the

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Institution directly or indirectly, whether in writing, electronic, oral or visual transmission, or which is developed under this Agreement.

14.2 Exclusions. Confidential Information does not include information that is in the public domain prior to disclosure by Lupin; becomes part of the public domain during the term of this confidentiality obligation by any means other than breach of this Agreement by Principal Investigator; is already known to Principal Investigator and the Institution at the time of disclosure and is free of any obligations of confidentiality; or is obtained by Principal Investigator and the Institution, free of any obligations of confidentiality from a third party who has a lawful right to disclose it.

14.3 Obligations of Confidentiality. Unless Lupin provides prior written consent, Principal Investigator may not use Confidential Information for any purpose other than that authorized in this Agreement, nor may Principal Investigator and the Institution disclose Confidential Information to any third party except as authorized in this Agreement or as required by law. Required disclosure of Confidential Information to the IEC or to an applicable Authority is specifically authorized.

14.4 Disclosure Required by Law. If disclosure of Confidential Information beyond that expressly authorized in this Agreement is required by Applicable Law, that disclosure does not constitute a breach of this Agreement so long as Principal Investigator and/or the Institution notifies Lupin or Lupin in writing as far as possible in advance of the disclosure so as to allow Lupin to take legal action to protect its Confidential Information, discloses only that Confidential Information required to comply with the legal requirement, and continues to maintain the confidentiality of this Confidential Information with respect to all other third parties.

14.5 Survival of Obligations. For Confidential Information other than Trial Data and Biological Sample Analysis Data, these obligations of nonuse and nondisclosure survive termination of this Agreement. Permitted uses and disclosures of Trial Data are described in Sections 18 (Publications) of this Agreement.

14.6 Return of Confidential Information. If requested by Lupin, Principal Investigator will return all Confidential Information, at Lupin's expense, except that required to be retained at the Study Site by Applicable Law. However, Principal Investigator may retain a single archival copy of the Confidential Information for the sole purpose of determining the scope of obligations incurred under this Agreement.

15. Trial Data, Biological Samples, and Records.

15.1 Trial Data. During the course of the Trial, Principal Investigator will collect and submit data to Lupin or its agent, as specified in the Protocol. This includes CRFs (or their equivalent) or electronic data records, as well as any other documents or materials created for the Trial and required to be submitted to Lupin or its agent, such as X-ray, MRI, or other types of medical images, ECG, EEG, or other types of tracings or printouts, or data summaries (collectively, "Trial Data"). Principal Investigator will ensure accurate and timely collection, recording, and submission of Trial Data.

a. Ownership of Trial Data. Subject to Principal Investigator's right to publish, with prior written intimation to Lupin, the results of the Trial and the non-exclusive license that permits certain uses, Lupin is the exclusive owner of all Trial Data.

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b. Non-Exclusive License. Lupin grants Principal Investigator a royalty free non-exclusive license, with no right to sublicense, to use Trial Data for internal research or educational purposes.

c. Medical Records. Medical records relating to Trial Subjects that are not submitted to Lupin may include some of the same information as is included in Trial Data; however, Lupin makes no claim of ownership to those documents or the information they contain.

d. Personal Information Protection. Each party represents and warrants that procedures compatible with relevant personal information and data protection laws and regulations will be employed so that processing and transfer of such information and data identifiers will not be impeded.

15.2 Biological Samples. If so specified in the Protocol, Principal Investigator may collect and provide to Lupin or its designee biological samples (e.g., blood, urine, tissue, saliva, etc.) obtained from Trial Subjects for testing that is not directly related to patient care or safety monitoring, including pharmacokinetic, pharmacogenomic, or biomarker testing ("Biological Samples").

a. Use. Principal Investigator will not use Biological Samples collected under the Protocol in any manner or for any purpose other than that described in the Protocol.

b. Sample Data. Lupin or its designees will test Biological Samples as described in the Protocol. Unless otherwise specified in the Protocol, Lupin will not provide the results of such tests ("Sample Data") to the Principal Investigator or Trial Subject. Sample Data will be treated as Trial Data; therefore, if Lupin provides Sample Data to the Principal Investigator, that data will be subject to the permitted use of Trial Data as outlined in this Agreement.

15.3 Records. Principal Investigator will ensure that Trial Subject's Trial records, which include the Principal Investigator's copies of all Trial Data as well as relevant source documents (collectively, "Records"), are kept up to date and maintained in accordance with Applicable Law.

a. Retention. Principal Investigator will retain all records and documents pertaining to the Trial for a period in accordance with Applicable Law and the Protocol. Principal Investigator will retain Records, under storage conditions conducive to their stability and protection, for a period of fifteen (15) years after termination of the Trial unless Lupin authorizes, in writing, earlier destruction. At the end of such required retention period, Principal Investigator will not destroy any such records until it has obtained Lupin's prior written permission to do so; provided, however, that if Lupin does not give written permission to Principal Investigator to destroy such records within thirty (30) days of Principal Investigator's request to Lupin, then Principal Investigator may forward all such records to Lupin, at Lupin's expense, or continue to retain such records. Principal Investigator further agrees to permit Lupin to ensure that the records are retained for a longer period if necessary, at Lupin's expense, under an arrangement that protects the confidentiality of the records (e.g., secure off-site storage). \

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16. Inspections and Audits.

16.1 Access. Upon reasonable request by Lupin, authorized representatives of Lupin, and/or authorized representatives of the applicable Authority, may during regular business hours examine and copy: all CRFs and other Trial records (including Trial Subject records and medical charts; Trial Subject consent documents; drug receipt and disposition logs); examine and inspect the facilities and other activities relating to the Trial or the IEC; and observe the conduct of the Trial.

16.2 Notice. Principal Investigator and/or the Institution will inform Lupin within twenty-four (24) hours of any effort or request by regulatory authorities or other persons to inspect or contact the Principal Investigator or research staff with regard to the Trial; will provide Lupin with a copy of any communications sent by such persons; and will provide Lupin or Lupin the opportunity to participate in any proposed or actual responses by Principal Investigator to such communications.

16.3 Cooperation. Principal Investigator and the Institution will ensure the full cooperation of the researchers and IEC members with any such inspection and will ensure timely access to applicable records and data. Principal Investigator will promptly resolve any discrepancies that are identified between the Trial Data and the Trial Subject's medical records. Principal Investigator will promptly forward to Lupin copies of any inspection findings that Principal Investigator receives from a regulatory agency in relation to the Trial. Whenever feasible, Principal Investigator will also provide Lupin with an opportunity to prospectively review and comment on any responses to regulatory agency inspections in regard to the Trial.

17. Inventions. If the conduct of Trial results in any invention or discovery whether patentable or not ("Invention"), Principal Investigator and/or the Institution will promptly inform Lupin. Principal Investigator will assign all interest in any such Invention to Lupin, free of any obligation or consideration beyond that provided for in this Agreement. Principal Investigator will provide reasonable assistance to Lupin in filing and prosecuting any patent applications relating to Invention, at Lupin's expense.

18. Publications. Principal Investigator acknowledges that Lupin has the right to use the Study Results in any manner deemed appropriate to Lupin's business interests, both during, and following termination/expiry of, this Agreement. Lupin shall have the sole right to retain the ownership of any and all data arising out of the conduct of clinical trials in relation to the Study. Upon completion of the Study, Lupin shall publish the results of the authorized clinical trial, either positive or negative, in scientific journals and with mention of the EC of clinical research that approved the study. Where Principal Investigator requires the use of the Study Results for publication, the Principal Investigator shall seek Lupin's written approval 90 (ninety) days in advance; such consent shall not be unreasonably withheld. If part of a multi-center trial, Principal Investigator agrees that the first publication is to be a joint publication involving all centers. Principal Investigator is free to decline to participate or be listed as an author in the joint publication. If a joint manuscript has not been submitted for publication within twelve (12) months of completion or termination of Trial at all participating sites, Principal Investigator is free to publish separately, subject to the other requirements of this Agreement.

19. Publicity. Neither party will use the name of the other party or any of its employees for promotional or advertising purposes without written permission from the other party. However, Lupin reserves the right to identify the Principal Investigator in association with a listing of the Protocol in the National Institutes of Health (NIH) Clinical Trials Data Bank, other publicly available listings of ongoing clinical trials, or other patient recruitment services or mechanisms.

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20. Indemnification.

20.1 Lupin agrees to indemnify and hold harmless ("Indemnify") the Principal Investigator, the Institution, its officers, agents, and employees; and the IEC that approved the Trial (collectively, "Indemnified Parties") against any claim filed by a third party for damages, costs, liabilities, expenses arising out of a Trial Subject injury, the design of the Trial, or the specifications of the Trial protocol. Trial Subject injury means a physical injury or drug-related psychiatric event caused by administration or use of Lupin Drug required by the Protocol that the Trial Subject would likely not have received if the Trial Subject had not participated in the Trial. Lupin further agrees to reimburse Principal Investigator for the reasonable cost of diagnostic procedures and medical treatment necessary to treat a Trial Subject injury. Principal Investigator agrees to provide or arrange for prompt diagnosis and medical treatment of any medical injury experienced by a Trial Subject as a result of the Trial Subject's participation in the Trial. Principal Investigator further agrees to promptly notify Lupin in writing of any such medical injury.

a. Exclusions. Excluded from this agreement to Indemnify are any claims for damages resulting from (a) failure by an Indemnified Party to comply with the Protocol or written instructions from Lupin (b) failure of an Indemnified Party to comply with any Applicable Law and governmental regulations, or (c) fraud, negligence or willful misconduct by an Indemnified Party.

b. Notice and Cooperation. Principal Investigator agrees to provide Lupin with prompt notice of, and full cooperation in handling, any claim that is subject to indemnification. If so requested by Lupin, Principal Investigator agrees to authorize Lupin to carry out the sole management of defense of an indemnified claim.

c. Settlement or Compromise. No settlement or compromise of a claim subject to this indemnification provision will be binding on Lupin without Lupin's prior written consent. Lupin will not unreasonably withhold such consent of a settlement or compromise. Neither party will admit fault on behalf of the other party without the written approval of that party.

20.2 Principal Investigator and the Institution shall jointly and severally indemnify and hold harmless Lupin including its directors, employees, representatives, agents etc., and shall be fully liable for all claims, damages, losses, liabilities, costs or expenses (including reasonable legal fees) resulting or arising from:

a. failure by the Principal Investigator and the Study Team (which shall include his/her employees, agents and representatives) to comply with the Applicable Law, the terms of this Agreement, ICH GCP and/or other nationally established guidelines, the approval of the IEC, Protocol or written instructions from Lupin;
b. any finding, requirement, determination or observation by any Authority (including but not limited to the FDA) which makes it necessary or desirable for Lupin to redo the Study;
c. failure by the Principal Investigator, the Study Team and/or the Institution to comply with Applicable Law;
d. any negligent act or omission or willful misconduct or fraud by Principal Investigator, the Study Team and/or the Institution, fraud or misrepresentation.

20.3 Except in the case of fraud, willful misconduct, gross negligence or breach of any Applicable Law, neither Party shall be entitled to incidental, indirect, consequential or special damages under any theory of Applicable Law arising in connection with such default or breach of the other Party's obligations under this Agreement, or any documents related thereto.

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20.4 In the event of any act of Principal Investigator and/or the Institution, which renders the Study invalid, to the extent Principal Investigator and/or the Institution is liable, Lupin shall, in addition to any other right that Lupin may have under law or equity, have the option at its sole discretion to either (a) request Principal Investigator to repeat the Study at Principal Investigator's own cost, or (b) require Principal Investigator and/or the Institution to promptly refund Lupin the compensation received by Principal Investigator and/or the Institution under this Agreement and bear any additional costs that Lupin may incur for repeating the Study. Further without prejudice to any other rights that Lupin may have under law or equity, Lupin may, at its discretion, forthwith terminate this Agreement.

21. Termination.

21.1 Termination Conditions. This Agreement terminates upon the earlier of any of the following events:

a. Disapproval by IEC. If, through no fault of Principal Investigator, the Trial is never initiated because of IEC disapproval, this Agreement will terminate immediately.

b. Trial Completion. For purposes of this Agreement, the Trial is considered complete after conclusion of all Protocol-required activities for all enrolled Trial Subjects; receipt by Lupin of all relevant Protocol-required data, Trial documents and Biological Samples; and receipt of all payments due to either party.

c. Early Termination of Trial. If the Trial is terminated early as described below, the Agreement will terminate after receipt by Lupin of all relevant Protocol-required data, Trial documents and Biological Samples and receipt of all payments due to either party.

(1) Termination of Trial Upon Notice. Lupin reserves the right to terminate the Trial for any reason upon thirty (30) days written notice to Principal Investigator.

(2) Immediate Termination of Trial by Lupin. Lupin further reserves the right to terminate the Trial immediately upon written notification to Principal Investigator and/or the Institution for causes that include – (i) failure to cure any breach within 15 days of written notice by Lupin notifying Principal Investigator of such breach; (ii) failure to enroll Trial Subjects at a rate sufficient to achieve Trial performance goals; (iii) material unauthorized deviations from the Protocol or reporting requirements; (iv) circumstances that in Lupin's opinion pose risks to the health or wellbeing of Trial Subjects; or (v) regulatory agency actions relating to the Trial or Lupin Drug or Comparator Drug.

(3) Immediate Termination of Trial by Principal Investigator. Principal Investigator reserves the right to terminate the Trial immediately upon notification to Lupin or Lupin if requested to do so by the responsible IEC or if such termination is required to protect the health of Trial Subjects.

21.2 Payment upon Termination. If the Trial is terminated early in accordance with this Agreement, Lupin will provide a termination payment equal to the amount owed for work already performed up to and including the effective date of termination, in accordance with Attachment-B, less payments already made. The termination payment will include any non-cancelable expenses, other than future personnel costs, so long as they were properly incurred and prospectively approved by Lupin, and, only to the extent such costs cannot reasonably be mitigated. If the Trial was never

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initiated because of disapproval by the IEC, Lupin will reimburse Principal Investigator for any other expenses that were prospectively approved, in writing, by Lupin.

21.3 Return of Materials. Unless Lupin instructs otherwise in writing, Principal Investigator will promptly return all materials supplied by Lupin, at Lupin's expense, for Trial conduct, and any Lupin-supplied Equipment. Principal Investigator will return and/or destroy, as required by Lupin, at Lupin's expense, unless otherwise specified by Lupin, any unused Lupin Drug or Comparator Drug.

22. Insurance. The Principal Investigator will secure and maintain in full force and effect throughout the performance of the Trial (and following termination of the Trial to cover any claims arising from the Trial) insurance coverage for medical professional liability with limits in accordance with local standards for all medical professionals conducting the Trial.

23. Debarment, Exclusion, Licensure and Response. Principal Investigator and the Institution jointly and severally certify that they are not debarred or restricted from conducting clinical research and will not use in any capacity the services of any person debarred or restricted from conducting clinical research under Applicable Law with respect to services to be performed under this Agreement. Principal Investigator and the Institution also certifies that they are not excluded from any governmental health care program. Principal Investigator and the Institution further certify that they are not subject to a government mandated corporate integrity agreement and has not violated any applicable anti-kickback or false claims laws or regulations. During the term of this Agreement and for three years after its termination, Principal Investigator and the Institution will notify Lupin promptly in writing to the extent possible, within two (2) business days if either of these certifications needs to be amended in light of new information or if Principal Investigator becomes aware of any material issues related to the medical licensure of any associated Trial researchers. Principal Investigator and the Institution will cooperate with Lupin regarding any responsive action necessary.

24. Assignment and Delegation. Lupin may at any time and upon written notice to Principal Investigator and/or the Institution assume the obligations and rights of Lupin or substitute Lupin with another independent contractor. None of the rights or obligations under this Agreement will be assigned or subcontracted by Principal Investigator and/or the Institution to another without the prior written consent of Lupin, and the express agreement of Principal Investigator and/or the Institution, Lupin, and the requisite new assignee or subcontractor. Principal Investigator and the Institution must notify Lupin, at least 90 (ninety) days in advance, prior to moving to another location. This Agreement will bind and inure to the benefit of the successors and permitted assigns of Lupin.

25. Equipment. Lupin may provide, or arrange for a vendor to provide, certain equipment for use by Principal Investigator during the conduct of the Trial ("Equipment"). Equipment use, ownership and disposition terms are further outlined in Attachment C.

26. Survival of Obligations. Obligations relating to Research Grant, Confidential Information, Inventions, Records, Publications, Publicity, Debarment and Exclusion, and Indemnification survive termination of this Agreement, as do any other provision in this Agreement or its Attachments that by its nature and intent remains valid after the term of the Agreement.

27. Entire Agreement. This Agreement contains the complete understanding of the parties and will, as of the Effective Date, supersede all other agreements between the parties concerning the specific Trial. This Agreement may only be extended, renewed or otherwise amended in writing, by the

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mutual consent of the parties. No waiver of any term, provision or condition of this Agreement, or breach thereof, whether by conduct or otherwise, in any one or more instances will be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or any prior, contemporaneous or subsequent breach thereof, of any other term, provision or condition of this Agreement whether of a same or different nature.

28. Conflict with Attachments. To the extent that terms or provisions of this Agreement conflict with the terms and provisions of the Protocol, the terms and provisions of this Agreement will control as to legal and business matters, and the terms and provisions of the Protocol will control as to technical research and scientific matters unless expressly agreed in a writing between the parties.

29. Relationship of the Parties. The relationship of Principal Investigator and/or the Institution to Lupin is one of independent contractor and not one of partnership, agent and principal, employee and employer, joint venture, or otherwise.

30. Force Majeure. Neither party will be liable for delay in performing or failure to perform obligations under this Agreement if such delay or failure results from circumstances outside its reasonable control (including, without limitation, any act of God, governmental action, accident, strike, terrorism, bioterrorism, lock-out or other form of industrial action) promptly notified to the other party ("Force Majeure"). Any incident of Force Majeure will not constitute a breach of this Agreement and the time for performance will be extended accordingly; however, if it persists for more than thirty (30) days, then the parties may enter into discussions with a view to alleviating its effects and, if possible, agreeing on such alternative arrangements as may be reasonable in all of the circumstances.

31. Governing Law. Subject to the terms of the Trial Conduct as outlined above, this Agreement shall be governed by and construed in accordance with the laws of India, without giving effect to conflict of law provisions. The Parties agree to submit all their disputes arising out of or in connection with this Agreement to the exclusive jurisdiction of the courts of Mumbai.

32. Notices. All notices required under this Agreement will be in writing and be deemed to have been given when hand delivered, sent by overnight courier or certified mail, as follows, provided that all urgent matters, such as safety reports, will be promptly communicated via telephone, and confirmed in writing:

TO LUPIN:
Attn. To: Dr Dhananjay Bakhle
Executive Vice President
Lupin Limited (Research Park)
Survey. No. 46A/47A, Village Nande,
Taluka Mulshi, Pune – 412115, Maharashtra, India

TO PRINCIPAL INVESTIGATOR:
Attn. To: Dr Sudhir Kulkarni
Mahatma Gandhi Mission Medical College and Hospital
N-6, CIDCO, Aurangabad – 431003,
Maharashtra, India

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TO INSTITUTION:
Attn. To: Dr Rajendra Bohra
Mahatma Gandhi Mission Medical College and Hospital
N-6, CIDCO, Aurangabad – 431003,
Maharashtra, India

In the event that the parties execute this Agreement by exchange of electronically signed copies or facsimile signed copies, the parties agree that, upon being signed by both parties, this Agreement will become effective and binding and that facsimile copies and/or electronic signatures will constitute evidence a binding Agreement with the expectation that original documents may later be exchanged in good faith.

[INTENTIONALLY LEFT BLANK; SIGNATURE PAGE FOLLOWS]

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ACCEPTED AND AGREED BY:

PRINCIPAL INVESTIGATOR

By:
Signature

Dr. Sudhir Kulkarni
Printed Name

principle investigator
Title

20 Aug 2017.
Date

ACCEPTED AND AGREED BY:

LUPIN LIMITED

LUPIN LIMITED MUMBAI

By:
Signature

DR. DHANANJAY BAKHLE
Printed Name

EXECUTIVE VICE PRESIDENT, MEDICAL RESEARCH
Title

14th Aug 2017
Date

ACCEPTED AND AGREED BY:

INSTITUTION

By:
Signature

Printed Name DR RAJENDRA BOHRA

Title DEAN

21 AUG 2017
Date

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ACCEPTED AND AGREED BY

SMO

By:
Signature

DR SUSHIL CHAUDHARY
Printed Name

DIRECTOR
Title

20/Aug/2017
Date

LUPIN OK LEGAL

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Attachment A

Protocol

The clinical Trial to be performed pursuant to this Agreement shall be that set forth in the Protocol dated 15 December, 2016 and incorporated into this Agreement attached hereto by reference in addition to all current and future amendments thereto, which is incorporated into this Agreement by reference and entitled:

Protocol # LRP/LNP1892/2016/007 "A Randomized, Double – Blind, Placebo – Controlled, Phase 2 Study to Assess the Efficacy, Pharmacokinetics, Pharmacodynamics and Safety of LNP1892 (Monotherapy) in Chronic Kidney Disease (CKD) Patients with Secondary Hyperparathyroidism (SHPT), On Dialysis and Not on Dialysis"

Attachment B

RESEARCH GRANT PAYMENT TERMS

B-1. General Terms. Principal Investigator ("Payee") will be paid the per patient grant amount as outlined on Attachment-D (Research Grant Worksheet) per Trial Subject properly enrolled in the Trial. This amount constitutes the full compensation for the work to be completed by the Principal Investigator, including all work and care specified in the Protocol for the Trial, along with all overhead and administrative services. No compensation will be available for Trial Subjects enrolled or continuing in the Trial in violation of the Protocol.

B-2. Payment Terms. Research grant payments for each Trial Subject will be made in Indian Rupees (INR) quarterly and based on approval of invoices submitted. Invoices will be issued by Payee upon notice delivered by Lupin. Payments will be made in accordance with eCRFs submitted and monitored, and in accordance with Attachment D "Research Grant Worksheet". Monitoring will occur based on site enrollment and completion of data entry. Payments will be made in quarterly installments on a pro-rata basis. Undisputed invoices will be paid by Lupin within 60 (sixty) days of such invoice issue date.

B-3. Non-Procedural Costs. Payee will be paid for additional non-procedural costs that are pre-approved by Lupin, as set forth in Attachment D. To request payment for such costs, Payee will remit an itemized invoice to Lupin or its designee with documentation and receipts substantiating agreed-upon pass-through expenses. Any non-procedural pass-through expenses will be invoiced only in the amount actually incurred with no mark-up, up to the maximum amounts shown in Attachment D.

B-4. Final Payment. At the conclusion of the Trial, all CRFs and Trial-related documents will be promptly made available for Lupin's review. The final payment will be paid once: all CRFs have been completed and received; data queries have been satisfied; all Lupin Drug is returned; and all close out issues are resolved and procedures completed, including final IEC notification. All queries must be resolved within five (5) days of receipt by Payee any time during the Trial. Lupin or its designee will perform final reconciliation of all payments made to date against total amount due and will promptly pay Payee amounts remaining unpaid, if any. Payee will promptly reimburse Lupin amounts overpaid within thirty (30) days of notification by Lupin or designee.

B-5. Taxes.

(1) All payments to Payee by Lupin will be subject to deduction of TDS.

(2) The Payee shall comply with all its obligations under applicable tax laws in force at the time, including all laws, rules and regulations under the Goods and Services Tax ("GST") regime ("GST Law"). In particular, the Payee shall pay its taxes and make all filings necessary under GST Law, including the GSTR-1 form, within the prescribed timelines. The Payee shall defend, indemnify and hold Lupin harmless against all losses, claims and liabilities arising out of any failure by the Payee to meet its obligations under GST Law, including any failure or error that results in denial of any tax credit under GST law to Lupin. The Payee shall fully co-operate with Lupin to respond to the relevant tax authorities' demands, and to resolve any mismatch of Lupin and the Payee's GST filings within the timelines prescribed under the GST Law.

(3) Payee acknowledges and agrees that it is solely responsible for the payment of any and all contributions and taxes imposed by any applicable Authority with respect to or measured by compensation paid to Payee under this Agreement. Lupin will not be responsible for the withholding or payment of any such required contributions or taxes. Payee accepts full

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responsibility for reporting all payments received, under this agreement, to the relevant taxation authorities as required by local regulations.

B-6. Screen Failures. A Screen Failure is a consented Trial Subject who fails to meet the screening visit criteria and is thus not eligible for enrollment into the Trial. Screen Failures will be reimbursed, if at all, as outlined in Attachment D, based on work completed pursuant to the Protocol.

B-7. Patient travel reimbursement. Lupin, will reimburse reasonable patient travel related expenses per trial subject visit, up to the maximum amount listed in the Attachment D. Any reimbursement exceeding this limit will require prior written Lupin approval. Any payment will be based on the invoice together with supporting documentation (i.e receipts) submitted to Lupin.

B-8. Administrative Start-up Fees. This is not applicable for this site.

B-9. Necessary Procedures. Payee will be reimbursed for valid necessary visits and procedures. Payment for any necessary procedure due to patient safety will be reimbursed at the agreed upon unit cost in the budget, or if there is no such unit cost in the budget, at the appropriate unit cost pre-approved by Lupin in writing, and will require a separate invoice with documentation for the medical necessity of the procedure. Where practicable, Lupin's prior written consent will be obtained, unless it will compromise the integrity of the Trial or affect Trial Subject safety, in which case Lupin will be notified as soon as practicable after the fact.

B-10. Payee. The research grant payments will be made to the following payee and address:

Payee Name: **Grapecity Research Solutions LLP**
Payee Address: **Block No. D/2, Prakash Hsg. Society, Near Kalewadi Fata, Thergaon, Pune – 411033, Maharashtra, India**
Payee GST Number: **AA270817044477Q**
Payee PAN No.: **AAPFG8186L**
Payee Bank Account Details: **Current Bank Account**
Bank Name: **ICICI Bank**
Bank Address: **Gulmohar Park, Plot no. 1 A ITI Road, Aundh Pune- 411007**
Bank Account Number: **007305009846**
IBAN Number: **NA**
IFSC Code: **ICIC0000073**
Email address for remittance information: **sushilrc.chaudhary@gmail.com**

In case of changes in the Payee's bank account details, Payee is obliged to inform Lupin in writing, but no amendment to this Agreement shall be required.

B-11. Invoices. All invoices must be issued and forwarded to the following as instructed:

Lupin Limited (Research Park),
Survey. No. 46A/47A,
Village Nande, Taluka Mulshi,
Pune – 412115, Maharashtra, India
Attn: Dr Rajesh Kumawat

Each invoice must contain: (1) Lupin name, (2) Protocol number, (3) Project code, (4) a summary of the reimbursement to be made in compliance with the Research Grant Worksheet, and (3) the

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GST Registration Number, (4) if GST reverse charge mechanism applies, the note "GST reverse charge applicable".

Payee will not receive any payments for pass through expenses whereby Payee has failed to produce actual copy invoices or other documentation clearly substantiating that the expenditures were actual, reasonable, and verifiable in the amount submitted for compensation.

Any invoices submitted by the Payee more than 45 (forty five) days after the database lock will not be reimbursed.

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Attachment C

EQUIPMENT USE, OWNERSHIP & DISPOSITION

1. Use. During the term of this Agreement, Principal Investigator may use Equipment only for purposes of this Trial.

2. Ownership. Until the termination of this Agreement, this Equipment remains the property of the respective vendors that have provided the equipment to Lupin and must be returned either within a reasonable period of time upon request by Lupin, not to exceed five (5) calendar days, or immediately upon termination of this Agreement. Principal Investigator agrees to return the Equipment in the manner directed by Lupin in substantially the same condition as when received by Principal Investigator. Principal Investigator agrees to be financially responsible for obtaining insurance to cover any loss or destruction to Equipment while in Principal Investigator's care, which exceeds ordinary wear and tear and/or lacks a reasonable causal relationship to proper performance of the Trial. Principal Investigator further agrees that unless otherwise authorized in writing by Lupin of this Trial, Principal Investigator will not alter the Equipment in any way. Principal Investigator must not install any components or software, if applicable, without express approval of Lupin. Any software provided to Principal Investigator may not be duplicated. Principal Investigator is not permitted to use the Equipment for any other purpose than for the performance of this Trial in accordance with the Protocol. Lupin shall not have any liability for damages of any sort, including personal injury or property damage, resulting from the use of Equipment except to the extent that such damages were caused by the negligence or willful misconduct of Lupin, as applicable, and except to the extent that a personal injury constitutes a compensable Trial Subject injury to be paid by Lupin as described in this Agreement.

3. Return to Lupin. After completion of Trial conduct or at an earlier time specified by Lupin, Principal Investigator will arrange for return of Equipment and Lupin materials, at Lupin's expense, to Lupin or a location designated by Lupin.

Attachment D

RESEARCH GRANT WORKSHEET

Grant Worksheet **Principal Investigator: Dr. Sudhir Kulkarni** **Protocol No.: LRP/LNP1892/2016/007**	
Main Study	
Investigator Grant Per Patient	***Cost (INR)***[1]
Screening (All activities per protocol)	9,000
Day 1 (All activities per protocol)	11,000
Day 8 (All activities per protocol)	4,000
Day 15 (All activities per protocol)	4,000
Day 30 (All activities per protocol)	11,000
Day 60 (All activities per protocol)	11,000
Day 90 (All activities per protocol)	11,000
Day 97 (All activities per protocol)	9,000
Total per patient amount - Main Study	**70,000**
PK PD Study	
Investigator Grant Per Patient	***Cost (INR)***[1]
Screening (All activities per protocol)	9,000
Day 1 (All activities per protocol)	6,000
Day 2 (All activities per protocol)	3,000
Day 8 / EOT (All activities per protocol)	6,000
Day 9 (All activities per protocol)	2,000
Day 10 (All activities per protocol)	2,000
Day 15 / FU Visit (All activities per protocol)	2,000
Total per patient amount - PK PD Study	**30,000**
TOTAL PER PATIENT GRANT AMOUNT (MAIN STUDY & PK PD STUDY)	**1, 00,000**

Additional Study Related Costs	***Cost (INR)***[1]
Screen Failures[2]	9,000
Patient travel reimbursement	500
12 Lead ECG (Only at Protocol scheduled time points)	500
Ultra-Sonography (USG) Neck (Only For Main study, Parathyroid Gland size assessment at protocol scheduled time points)	1,800
Hospital Per day charges (Night stay) (As per PK PD protocol schedule only)	2,800

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Hemodialysis cycle (Post randomization per cycle cost, Only for patients randomized on hemodialysis arm)	2,800
Institutional Overheads[3]	10%

Invoiced Charges[4]	*Cost in INR*[1]
Archival Fees (For 15 Years)	30,000
TOTAL Invoiced Charges	**30,000**

Notes:
[1]Total Costs are inclusive of indirect cost.
[2]Ratio: 1:1 (One (1) Screen Failure for every one (1) subject randomized into the Study. Screen Fails are
[3]Institutional Overheads would be calculated per total investigator grant payment and would be paid as a part of each quarterly payment.
[4]Invoiced Charges to be paid upon receipt of invoice from Principal Investigator, before site close out.

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