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CLINICAL TRIAL AGREEMENT

THIS CLINICAL TRIAL AGREEMENT is made on this 12 Day of Jan 2016 by and between,

Veeda Clinical Research Pvt. Ltd, an Indian Company having its principal place of business at Shivalik Plaza–B, Nr. I.I.M., Ambawadi, Ahmedabad – 380 015 Gujarat (hereinafter referred to as the "Veeda") which shall include its successors, assigns, representatives, affiliates, and subsidiaries,

And

Dr. Chandrasekhar Tamane ("Principal Investigator"), having its place of work at **MGM Medical College & hospital, N-6 CIDCO, Aurangabad 431003, Maharashtra.**

And

MGM Medical College & hospital ("Institution") having its principal place of business at **N-6 CIDCO, Aurangabad 431003, Maharashtra.** (Hereinafter referred to as the "Institution") which shall include its successors, assigns, representatives, affiliates, and subsidiaries.

WHEREAS, Veeda is a contract research organization contracted by Biocon Limited, SEZ unit, Biocon Special Economic Zone, Plot No.2&3, Phase IV- B.I.A, Bommasandra-Jigani Link Road, Bangalore - 560099, India (herein after referred to as "Sponsor") to perform one or more of sponsor study related duties and functions for the Project No. 15-VIN-155 entitled " A randomized, multi center, open label, two-treatment, two-period, two-sequence, multiple dose, crossover, steady state bioequivalence study of Everolimus tablets, 10 mg of Biocon Limited, India vs. Afinitor® (Everolimus) tablets, 10 mg of Novartis Pharmaceuticals Corporation, USA in advanced renal cell carcinoma (RCC) patients."; and

WHEREAS, Principal Investigator is properly qualified and experienced and working at Institution and Principal Investigator has the authority and desire to conduct the Study at the Institution; and

WHEREAS, Institution has adequate infrastructure to conduct the Study and allowed Principal Investigator and Veeda to conduct the Study;

NOW THEREFORE, in consideration of the mutual covenants contained in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties, intending to be legally bound, agree as follows:

1. DEFINITIONS

1.1 Definitions. As used in this Agreement, each capitalized term listed below shall have the meaning that is given after it:

- "Budget" means the detailed budget established for the Study, as detailed in Exhibit B, which is incorporated herein by reference.
- "CRF" or "Case Report Form" means a printed, optical, or electronic document designed to record all of the Protocol required information to be reported to Sponsor on each Subject.
- "Data" shall mean all information, reports, records, and documents generated under this Agreement excluding subject medical records. Data shall be the sole and exclusive

MGM's Medical College Aurangabad

Veeda Clinical Research Ahmedabad

property of Sponsor and may be freely utilized by Sponsor and their representatives. Sponsor may freely assign its rights to and interests in any Data to a party of the Sponsor's choice.

- "Financial Disclosure Certification Form" means the financial disclosure certification attached as Exhibit B, to record compliance with 21 CFR Part 54 (U.S.).
- "ICH Guidelines" means the International Council for Harmonization, Harmonized Tripartite Guideline for Good Clinical Practice E6, 1996, or such successor provisions in force at the time of performance of the services.
- "IEC" means the Independent Ethics Committee/Institutional Ethics Committee ("IEC"), as the term is defined in ICH Guidelines and any other review board required by applicable law or ICH Guidelines.
- "Informed Consent" means a consent signed by or on behalf of a Subject which consent shall comply with the applicable local law and the regulations of the U.S. Department of Health and Human Services, its supporting agencies, the FDA and any other applicable regulatory agency governing informed consents including without limitation, Schedule Y, Section 4.8 of the ICH Guideline, 45 CFR §46.116(a), 21 CFR Part 50 and 21 CFR Part 812.
- "Protocol" means the document that specifies the clinical trial procedures, as developed by Sponsor applicable for the performance of a Study and any amendments thereto. Protocol shall be attached to this Agreement as Exhibit A.
- "Study Product" means Everolimus tablets, 10 mg of Biocon Limited, SEZ unit, Biocon Special Economic Zone, Plot No.2&3, Phase IV- B.I.A, Bommasandra-Jigani Link Road, Bangalore - 560099,India an investigational drug.
- "Subject" means an individual who meets all eligibility criteria, is properly consented and enrolled in the Study.

2. Scope

2.1 This Agreement allows the parties to specify distinct clinical study activities to be performed by Principal Investigator and Institution for the Study.

2.2 Conduct of Study Principal Investigator and Institution shall conduct the Study pursuant to the terms of this Agreement and in strict adherence to the Protocol, as the same may be amended from time to time in writing by Sponsor, and any other written instructions that may be provided from time to time to Principal Investigator by Sponsor. Prior to conducting the Study, the Principal Investigator shall review and understand the Protocol, as evidenced by the Principal Investigator's signature on the "Investigator Agreement(s)" contained within the applicable Protocol, all of which are incorporated herein by reference.

2.3 Principal Investigator.

2.3.1 Principal Investigator shall be personally responsible for the conduct of the Study. If such personal services are not available for any reason, Veeda or Sponsor may terminate this Agreement immediately without any further financial obligation to Principal Investigator and / or Institution.

2.3.2 Principal Investigator agrees to return to Veeda any unearned or unaccounted for amounts paid by Veeda that exceed the amount to which Principal Investigator are entitled hereunder.

2.3.3 During the performance of the Clinical Trial and / or for a period of 15 years after termination of the agreement, the Principal Investigator is responsible for, but not be limited to, the

following aspects:

a) Provision of required study documents (e.g. curriculum vitae(s), medical registration certificates and/or other relevant documents evidencing qualifications of Investigator(s) and sub-Investigator(s), confirmation of adequate site facilities, etc.);
b) Progress reporting (including recruitment figures) to Ethics Committee and Veeda on a regular basis;
c) Ensuring reasonable access by monitors, auditors and regulatory authorities to Principal Investigator and other project personnel, project facilities, original study materials, drug records, subject records, case reports, and other records; subject to applicable laws and regulations; and providing appropriate working conditions for monitors, auditors and regulatory authorities to perform study-related monitoring, audit and inspection;
d) To allow any regulatory audit by DCGI or any applicable regulatory authorities within 15 years of submission of report and ensure compliance of any regulatory deficiency raised by such authorities in reasonable period of time; If Principal Investigator is to submit any information to such regulatory authorities agencies, such submissions shall not be made without Veeda's prior review and written approval, and any changes (other than entry of required information) also shall be subject to such prior written approval.
e) Safe handling, storage, transportation and disposal of infectious materials and wastes involved in the Clinical Trial;
f) Inform the Ethics Committee of study closure;
g) Maintenance of drug accountability records, study documents including study drug acknowledgement receipts, study supply receipts, payment receipts, EC approvals etc.;
h) Handling and storage of compound according to protocol; and
i) Storage of site file and all the trial related data for a period of 15 years after completion of the study without any additional cost / compensation / grants. At their discretion the Institution / Investigator at their own cost will make arrangements to store the site file and all the trial related data at the authorized third party location.
j) The Principal Investigator is responsible for training and supervision of sub-Investigators and other site study team member on the procedures specified in the Protocol to ensure scientific, technical, and ethical conduct of the Clinical Trial. In case of any personnel changes, the Principal Investigator is responsible for notifying Veeda of such change in a timely manner.

2.3.4 The review of serious adverse events shall be undertaken by Veeda in close coordination with Principal Investigator. "Serious" as used in this section, refers to an experience which results in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect. "Unexpected" as used in this section, refers to conditions or developments not previously submitted to governmental agencies or encountered during clinical studies of the Product, and conditions or developments occurring at a rate higher than shown by information previously submitted to an agency or other governmental agencies or encountered during clinical studies of the Product or, if applicable, conditions or developments not identified in the approved Product information circular, and includes any other meaning under applicable law.

2.3.5 Veeda shall have the right, to monitor or visit the Principle Investigator and audit the Trial with respect to the services provided hereunder with / without the Sponsor. Principal Investigator will cooperate with Veeda and the Sponsor and provide a current status of the trial.

2.3.6 The Principle Investigator is responsible for reporting, and shall report, all such findings in the manner and within the time limits as set out in the applicable provisions of ICH GCP and the applicable legislation. The Principle Investigator shall strictly adhere to the SAE reporting timeline as per the current regulations of licensing authority (DCGI), requirement of ICH GCP, current Schedule Y.

The investigator will be responsible to report any SAE to the licensing authority, Sponsor's representative, CRO representative and chairman of Ethics Committee within 24 hours of identifying the event as SAE.

In case of SAE other than death the investigator will send the detailed report within 10 calendar days of SAE to the licensing authority, chairman of Ethics Committee where the SAE has occurred, and the head of the institution where the trial is being conducted.

In case of SAE of death the investigator will send the detailed report within 10 calendar days of SAE to the chairman of Ethics Committee, chairman of the expert committee constituted by the licensing authority with a copy to licensing authority and the head of the institution where the trial is being conducted.

Notwithstanding anything in this Agreement to the contrary, the Principal Investigator and the Institution shall have the right to disclose findings that could adversely affect the safety of Clinical Trial subjects to the Ethics Committees of participating sites, and appropriate regulatory authorities if they deem it necessary to protect the health of study participants, provided that Veeda is copied on such reports.

2.3.7 The Principle Investigator shall participate in teleconferences required by Veeda to update the study product information and resolve issues, if any.

2.3.8 The Principle Investigator and/or the Institution, Veeda and Sponsor shall comply with all regulatory requirements relating to the retention of records and shall maintain all such records, and make them available for inspection, and shall allow Sponsor and all applicable authorities in charge of the Clinical Trial to inspect such records, including the patient's medical records. The Site Investigator File containing the essential documents and source data must be archived for at least fifteen (15) years following completion of the study at the Site or such other authorized facilities as agreed between Veeda, the Principle Investigator and the site. The Principle Investigator and /or the Institution shall inform Sponsor in the event of relocation or transfer of archiving responsibilities. At their discretion the Institution / Investigator at their own cost will make arrangements to store the site file and all the trial related data at the authorized third party location.

2.3.9 In the event that the Principle Investigator is to destroy the Investigator Site File or source data, the Principle Investigator should inform Veeda prior to destruction to confirm it is acceptable for them to be destroyed.

2.3.10 Investigational Medicinal Product i.e. both unused and retention samples will be retained at the site after completion of the study for a desired period, as per USFDA/sponsor requirement and also as per the written instruction given by Veeda/Sponsor at free of cost. The samples will be retained for a period of at-least 5 years following the date on which the application or supplemental application is approved, or, if such application or supplemental application is not

approved, at-least 5 years following the date of completion of bioavailability study in which the sample from which the reserve sample was obtained was used. Investigational Medicinal Product i.e. both unused and retention samples will continue to remain at the site unless further information is received from Veeda/Sponsor.

2.3.11 Principal Investigator/ Institute will intimate to CRO and Sponsor about any inspection/s from any regulatory authorities for the study, within 48 business hours of their notification.

2.4 Compliance with Law. Principal Investigator and Institution represent that they shall comply with all applicable laws in performing its obligations under this Agreement. Principal Investigator will assume all those responsibilities assigned to principal investigators under all applicable laws, rules, regulations, guidelines and standards including, without limitation, all relevant ICH Guidelines and standards, and all applicable laws relating to the confidentiality, privacy and security of patient information. In furtherance of the foregoing obligation, Principal Investigator shall ensure that timely report is sent to the IEC for the progress and conduct of Study. Principal Investigator and Institution, as applicable, shall comply with the directives of the IEC respecting the conduct of the Study, and shall immediately notify Veeda and Sponsor to the extent any such directives vary from the Protocol. Principal Investigator shall obtain from each Subject, prior to the Subject's participation in the Study, a signed Informed Consent and necessary authorization to disclose health information to Sponsor in a form approved in writing by the IEC and in conformity with local regulations and Sponsor's requirements therefore set forth in the Protocol.

2.5 Study Supplies. Veeda shall provide Principal Investigator with a sufficient quantity of Study Product to conduct the Study, as well as any other compounds, materials and information which the Protocol specifies. All such Study Product, compounds, materials and other information are and shall remain the sole property of Sponsor/Veeda. Principal Investigator and Institution, as applicable, shall ensure that the Study Product is stored and handled in accordance with protocol, all applicable laws in addition to any specific instructions from Sponsor and/or Veeda. Principal Investigator and Institution shall not use the Study Product past the labeled expiration date and shall not use the Study Product for any purpose other than the performance of the Protocol. In addition, upon completion or premature termination of the Study, Study Product shall be returned or destroyed pursuant to the procedures to be provided by Veeda and/or Sponsor.

Veeda on behalf of sponsor will provide the study-specific documents, e.g. Investigator Site File, Case Report Form, etc. to the Investigator before commencement of the Clinical Trial.

2.6 Delivery of Essential Documents and Reports. Principal Investigator shall provide to Veeda all Essential Documents (to be designated as such by Veeda) within two (2) weeks of Principal Investigator's receipt of IEC's written approval. If all Essential Documents have not been timely executed and received by Veeda, Veeda may terminate this Agreement immediately upon written notice. Principal Investigator shall submit written reports, as directed *by* Veeda and/or Sponsor, on the progress of the Study. Within thirty (30) days following the completion or premature termination of the Study, Principal Investigator shall furnish Veeda with the IEC report, notification as required by IEC on the Study prepared by the Principal Investigator, as well as all completed, used and unused CRFs not already delivered to Veeda, and all Data, reports and other information generated in relation to the Study, as well as all other materials and information provided by Veeda and/or Sponsor, unless Veeda and/or Sponsor directs otherwise in writing.

2.7 Monitoring of Study. Principal Investigator and Institution shall permit Veeda and/or Veeda

designee(s) including but not limited to Sponsor access to Institution, during regular business hours with reasonable prior notice, to monitor the conduct of the Study as well as to audit records, CRFs, Data and other information and documents relating to the Study, in order to verify Principal Investigator's compliance with their obligations herein. If any governmental entity should audit or inspect the Institution with respect to the Study, Principal Investigator and/or Institution shall provide Veeda and Sponsor with immediate notice and shall provide an opportunity for Sponsor or its designee to be present during such governmental audit.

2.8 Contract Research Organizations/vendors. Subject to Sponsor's approval, Veeda may retain one or more contract research organizations ("CRO")/vendor to assist them in managing and monitoring the Study. Principal Investigator and Institution acknowledge Veeda's right to assign or transfer, in whole or in part, without the consent of the Principal Investigator and Institution, any of its rights or obligations under this Agreement to any such CRO or vendors. The Principal Investigator and Institution shall permit such CROs/vendors to perform any or all of Veeda's obligations, or to exercise any or all of Veeda's rights, under this Agreement.

2.9 No Reimbursement for Sponsor Paid Drug or Services. Principal Investigator and Institution agrees that, if Study Product and/or other services are paid for or provided without charge by Sponsor or Veeda, Principal Investigator, Institution and/or any other vendor subcontracted or engaged by Principal Investigator or Institution shall not separately bill or seek reimbursement for such Study Product and/or services from any third party including, without limitation, the Subject, any private provider of Insurance or state program. Principal Investigator and Institution further agree that they shall accurately report receipt of such Study Product to any government or private insurance program, as may be required by law.

2.10 Financial Disclosure Certification. Principal Investigator or Institution, as applicable, shall ensure that any sub investigators connected with the Study, complete and return to Veeda and/or Sponsor the Financial Disclosure Certification Form prior to the initiation of the Study. Principal Investigator or Institution, as applicable, shall require any sub investigators to promptly notify Veeda and/or Sponsor of any change in the accuracy of the Financial Disclosure Certification Form during the term of Study and for one (1) year following completion of the Study. In addition, Principal Investigator or Institution, as applicable, shall comply with all applicable requirements of the National Institutes of Health and the Public Health Service regarding reporting and management of conflicts of interest.

3. COMPENSATION

3.1 Payment. Veeda shall pay Principal Investigator/Institution the amounts set forth in Exhibit B for Subjects properly enrolled, completed visits and CRFs completely and accurately returned to Veeda and/or Sponsor. All payments shall be payable in Indian Rupees and made within forty five (45) days of receipt and approval of an invoice for Institution /Principal Investigator's services.

The parties hereto agree as follows:

a) Veeda will pay a sum for every complete and evaluable patient as defined in the payment schedule for "Per Patient Fee".
The "Per Subject Fee" is a fixed fee per patient which includes all costs and honoraria, including, but not limited to:
    - all study related activities such as conduct of visits and Source & CRF completion
    - time and effort of Principle Investigator and other site staff

- study coordinator salary
- all diagnostic tests and other investigations (ECG, X-ray Chest etc)
- housing or hospital stay for patients including meals
- Patient conveyance/compensation
- miscellaneous (telephone, fax, courier, etc)
- all overhead costs

b) A complete and evaluable patient is defined as follows:
   - all procedures must be performed according to the protocol
   - a patient will only be included according to the inclusion/exclusion criteria
   - all data are documented accurately, completely

c) All payments will be on a *pro rata* basis. For patients who do not complete (early termination, drop-out, etc), the payment schedule will be evaluated according to the number of days completed.

d) Invoice will be generated / requested for payment on monthly basis according to the actual work performed (after source data verification and CRFs retrieval for completed visits). Invoice will be generated / requested according to milestone specified above. The final payment (20%) will be made at the time of site closeout visit or immediately after site close-out visit.

e) Any third parties designated by you (including Radiology, Local Laboratory, etc) will be managed and paid by you.

f) The Ethics Committee fee will be paid by Veeda, and is separate from the per-patient grant. Details of the payment are as mentioned below.
   - Name of Ethics Committee: **MGM Ethics Committee for Research on Human Subjects**
   - Relationship between the site/institution and Ethics committee: **Institutional Ethics Committee**
   - Ethics committee payee name: **MGM Medical College, Aurangabad**
   - Relationship between the Ethics committee and the Ethics committee payee name, if it is different from Ethics committee as mentioned in the SOP: **NA**
   - PAN no. of the payee: **AAATM4256E**
   - Ethics Committee Fees: Rs. **(Excluding TDS): INR 40000/-**

g) Screen failure patient's visit will be paid ONLY if the patient is screen failure based on results or reports of laboratory investigations, ECG, X-ray Chest, and SAE or in case patient withdrew consent.

h) If patient was randomized in the study deviating from protocol inclusion and exclusion criteria (without waiver, if applicable) then payment will not be made for such wrong randomization and subsequent visits, however screening visit can be paid, if performed according to protocol.

i) Patient conveyance will pay by Veeda, and is not included in per patient fees.

j) Veeda will manage SAE reimbursement for medical management expenses towards AE/SAE directly to the patient or LAR and SAE compensation payment directly to the patient / LAR with prior written approval from the sponsor and will get for reimbursement for those expenses.

k) Veeda will pay the Institution an upfront amount of INR 20,000/- once 1st patient is enrolled / randomized. This upfront amount will be adjusted form subsequent payment(s). In case site is not able to enrol any patients then Principle Investigator / Institute is liable and must return upfront amount immediately without any delay.
   Details of Payee are:

Name of Payee: MGM Medical College, Aurangabad
PAN No. : AAATM4256E

MGM's Medical College Aurangabad

Veeda Clinical Research Ahmedabad

Note: All the payments made to the payee are subject to Withholding Tax (Tax Deducted at Source (TDS)) as applicable from time to time and Veeda will deduct the tax at the time of making payments.

3.2 Disputed Payment. Principal Investigator/Institution agrees that in the event of a dispute regarding Sponsor's approval of documentation of supporting costs incurred under this Agreement, data and information resulting from Institution's (including Principal Investigator) participation in Study cannot be withheld by Institution's (including Principal Investigator) pending resolution of the dispute. Veeda and Principal Investigator/Institution agree to use reasonable efforts to resolve any disputes in a timely manner.

3.3 Overpayment/Underpayment. If, at the date of Study termination, the total amount paid to Principal Investigator/Institution exceeds the amount to which Principal Investigator/Institution is entitled, Principal Investigator/Institution shall return the overpayment to Veeda within forty-five (45) days from the termination date. If, at the date of termination, the total amount paid to Principal Investigator/Institution is less than the amount to which Principal Investigator/Institution is entitled, Veeda shall pay the amount due to Principal Investigator/Institution within forty-five (45) days following termination of the Study, delivery to Veeda and/or Sponsor of the remaining CRFs, final reconciliation of any remaining amounts due, and the return to Veeda of all items described in Section 2.7 above.

3.4 Commercially Reasonable Efforts. The Principle Investigator and/or the Institution shall use all reasonable endeavors to enroll maximum Eligible Cases as soon as possible. The parties may agree in writing to extend the time for recruitment of eligible patients if so desired. Recruitment period will be of 2 months however recruitment will be competitive among participating sites hence the site may have recruitment period even less or more then specified.

Principal Investigator/Institution shall use reasonable efforts to complete enrollment of study subjects within two months (2) months after receiving a go ahead from the sponsor/veeda to enroll patients in the study. Veeda may terminate this Agreement upon written notice, if Principal Investigator/Institution is not able to enroll any patient for a month following Study initiation at their site and in that case, the Principal Investigator / Institution is responsible to refund the all amount paid till the date of termination of the agreement within 1 month from the date of intimation of termination of the agreement.

Allowed screen failure rate in the study is 10 %, hence the investigator should put in reasonable efforts to recruit eligible cases in the study.

3.5 Remittance of Payment. All payments to Principal Investigator/Institution and any other party as defined in this agreement made pursuant to this Agreement shall be made by Veeda and all study related payments will be made by cheque and sent to:

Trial Payee Address: MGM Medical College, N-6 CIDCO, Aurangabad. 431003. Maharashtra. INDIA

3.6 Relationship of Parties. Veeda shall be responsible for all payments to Principal Investigator/Institution pursuant to this Agreement but such responsibility is subject to receipt of funds from Sponsor. Upon receipt of such funds by Veeda from Sponsor, Principal Investigator /

Institution shall have no recourse against Sponsor or any of its subsidiaries or affiliates for Veeda's breach of its payment obligations to Investigator pursuant to this Agreement.

4. CONFIDENTIALITY

4.1 Confidentiality & Non-Use Obligation. During the Study's performance and for Five years (5) years thereafter, Institution, its employees, agents, and subcontractors (if any) and Principal Investigator shall not disclose Confidential Information (hereinafter defined) for any purpose other than as indicated in this Agreement without Sponsor's prior written consent.

4.2 Definition of Confidential Information. Subject to Principal Investigator's publication rights as set forth in Sections 6.1 and 6.2, " Confidential Information" shall include the Protocol, CRFs, Data, Study Product, and all materials and information in whatever form or medium (whether now known or in the future developed) and however communicated, be it by written, verbal, visual, machine readable form, or in the form of biological materials or samples, or in any other form, relating, directly or indirectly, to Sponsor and the Study disclosed to Principal Investigator and/or Institution by Sponsor or Veeda or developed by Principal Investigator or Institution as a result of conducting the Study. Confidential Information shall also include any confidential information obtained under a confidentiality agreement with a third party, which Sponsor is permitted to disclose to Principal Investigator and/or Institution.

4.3 Exceptions to Obligation of Confidentiality and Non-Use. Principal Investigator and Institution's obligation of confidentiality and non-use described in Section 4.1 applies to all Confidential Information, except any portion thereof which:

(i) Is known to Principal Investigator and Institution, its employees, agents, or subcontractors before receipt thereof under this Agreement, as evidenced by written records;

(ii) is disclosed to Principal Investigator and/or Institution, their employees, agents, or subcontractors after acceptance of this Agreement by a third party who has a right to make such disclosure in a non-confidential manner;

(iii) is or becomes part of the public domain through no fault of Principal Investigator or Institution , their employees, agents, or subcontractors; or

(iv) is independently developed by Principal Investigator or Institution, their employees, agents, or subcontractors, without reference to, use of, or disclosure of Confidential Information, as evidenced by written records.

4.4 Disclosure Required by Law. Nothing in this Agreement shall be construed to restrict Principal Investigator or Institution from disclosing Confidential Information as required by law or court order or other governmental order or request, provided in each case Institution and/or Principal Investigator shall timely inform Veeda and Sponsor and use all reasonable efforts to limit the disclosure and maintain the confidentiality of such Confidential Information to the extent possible. In addition, Institution and Principal Investigator shall permit Veeda and/or Sponsor to attempt to limit such disclosure by appropriate legal means.

4.5 Subject Confidentiality. The parties agree to abide by all applicable laws and regulations regarding Subject confidentiality. Principal Investigator is responsible for obtaining from each Subject, prior to the Subject's participation in the Study, a signed Informed Consent in a form

approved in writing by the IEC and in conformity with Sponsor's guidelines. Before requesting an individual's consent to participate in clinical trial the Principal Investigator must provide the individual with the trial information in a language that is non- technical and understandable by the study subjects and the same shall be recorded through audio-visual means.

During the audio-visual recording of informed consent process, the identity and records of the trial subjects are as far as possible kept confidential; and that no details about identity of said subjects, which would result in the disclosure of their identity, are disclosed without valid scientific and legal reasons which may be essential for the purposes of therapeutics or other interventions, without the specific consent in writing of the subject concerned, or someone authorised on their behalf, and after ensuring that the said subject does not suffer from any form of hardship, discrimination or stigmatisation as a consequence of having participated in the trial.

The Investigator must safeguard the confidentiality of trial data, which might lead to the identification of the individual subjects. Data of individual subjects can be disclosed only in a court of law under the orders of the presiding judge or in some cases may be required to communicate to Drug regulatory/ Health authority.

Prior consent of the subject should be taken for audio-visual recording of informed consent process and the same should be documented by the Investigator. Such consent may be taken orally. Only those subjects who give the consent for the AV recording shall be included in the clinical trial.

5. INTELLECTUAL PROPERTY

5.1 Inventions. All inventions whether or not patentable, discoveries, techniques, ideas, trade secrets, new uses, improvements, processes, compounds, products, and all other works that are conceived or reduced to practice during the course of performing the Clinical Trial by Principal Investigator and Institution (including but not limited to their employees, agents and/or any other vendor subcontracted or engaged by Principal Investigator or Institution) ("Intellectual Property") shall be promptly disclosed to Veeda and Sponsor and shall be the sole property of Sponsor; provided however, that Principal Investigator and Institution will have a fully-paid-up, royalty-free, perpetual, nonexclusive right without the right to sublicense, to make, have made, and use any Intellectual Property created hereunder for its own internal, noncommercial research, noncommercial patient care, and academic purposes. Principal Investigator and Institution agree, upon Sponsor's written request and at Sponsor's expense, to execute such documents and to take such other reasonable actions as Sponsor deems necessary or appropriate to obtain patent or other proprietary protection in Sponsor's name covering any Intellectual Property. Sponsor may freely assign its rights to and interests in any Intellectual Property to a party of the Sponsor's choice.

6. PUBLICATIONS

6.1 General procedures. If Principal Investigator prepares any presentation or publication, Principal Investigator is to provide Sponsor with a draft of the same for Sponsor's review and comment at least sixty (60) days prior to publication or presentation so that Sponsor may ascertain whether any Intellectual Property or other patentable Subject matter or Confidential Information are disclosed therein. Sponsor shall return comments to Principal Investigator within thirty (30) days after receipt of the draft presentation or publication ("Review Period"). In addition, Principal Investigator shall delay any proposed publication/presentation an additional sixty (60) days in addition to the Review Period in the event Sponsor so requests to enable Sponsor to secure patent or other proprietary protection ("Delay Period"). The Principal Investigator shall keep the proposed

publication confidential until the Review Period concludes and, if elected by Sponsor, the Delay Period has expired. The Principal Investigator understands that, with respect to any proposed publication or presentation, good faith consideration will be given to Sponsor's comments with due regard for Sponsor's commercial and proprietary interests and at Sponsor's request, any Confidential Information will be deleted from such article or presentation. Notwithstanding the foregoing, unless otherwise permitted in writing by Sponsor / Veeda, the Principal Investigator shall not be permitted to publish Confidential Information. For the purposes of this provision, Confidential Information shall not include the results of the Study. Institution shall have no right to publish or present pursuant to this Agreement.

6.2 Multi-Center Studies. It is agreed and understood by Principal Investigator that Study is a multi-center study and an independent, joint publication is anticipated to be authored by investigators in the multi-center study, including Principal Investigator. Therefore, Principal Investigator agrees not to publish or present the results or any information derived from the study without prior approval from the sponsor.

7. TERM & TERMINATION

7.1 Termination by Sponsor/Veeda. Veeda or Sponsor may terminate this Agreement (i) immediately if the Study is terminated by regulatory authorities or in the interest of public health; or (ii) without cause at any time during the Term of this agreement on thirty (30) days prior written notice to Institution and Principal Investigator.

7.2 Effect of Termination. Termination or expiration of this Agreement shall not affect any rights or obligations which have accrued prior thereto. In the event of termination of this Agreement, Principal Investigator and Institution shall complete the Study for then-enrolled Subjects where required by accepted medical practice.

8. INDEMNIFICATION

8.1 Sponsor Indemnification. Sponsor shall indemnify Principal Investigator and Institution, (including Principal Investigator's and Institution's affiliates, contractors, agents, fellows, employees and servants) (collectively "Investigator Indemnitees") for any damages and liabilities, including reasonable attorney's fees incurred by Investigator Indemnitees as a result of any claim or lawsuit against them arising directly out of the performance of the Study drug pursuant to the Protocol ("Claims"); provided however Sponsor will not be responsible for and assumes no liability for any loss, claims, and/or demands to the extent arising from any of the following: the negligence or willful misconduct of an Investigator Indemnitees or any Investigator Indemnitees failure to adhere to (i) the terms of the Protocol and/or this Agreement including any amendments thereto; or (ii) applicable federal, provincial, or local laws; or (iii) the written instructions relative to the use of the Study Product.

8.2 Institution Indemnification. Institution shall indemnify, defend and hold harmless Sponsor and Veeda (including Sponsor's and Veeda's affiliates, contractors, agents, fellows, employees and servants) (collectively "Sponsor Indemnitees") from any and all losses, injuries, harm, costs or expenses, including without limitation, reasonable attorney's fees, incurred by Sponsor Indemnitees that arise from the negligence or willful misconduct by Investigator Indemnitees (as defined above in clause 8.1). Principal Investigator and Institution shall carry professional Indemnity Insurance and such other insurance required to indemnify under this clause, for the duration of this Agreement and for a reasonable period (which is not less than 1 year) after

termination or expiration thereof. Principal Investigator and Institution shall provide the copy of insurance as and when required by Veeda or Sponsor.

8.3 Obligation to Notify. The foregoing agreement to indemnify is conditioned upon the obligation of the Indemnitee to:

(i) advise indemnifying party of any claim or lawsuit, in writing, within fifteen (15) days after Indemnitee has received notice of said claim or lawsuit, or within such other time frame so that indemnifying party's ability and rights to defend or settle such claim or lawsuit, as determined in Sponsor's sole discretion, are not prejudiced;

(ii) Assist indemnifying party and its representatives in the investigation and defense of any lawsuit and/or claim for which indemnification is provided; and

(iii) Not compromise or otherwise settle any such claim or lawsuit on behalf of indemnifying party without indemnifying party prior written consent.

8.4 Serious Adverse Event Reimbursement. Not withstanding any other terms contained in this Agreement, Sponsor will reimburse the Institution for any reasonable, necessary and properly documented medical expenses directly related to a Subject's Serious Adverse Event (as the term is defined in the Protocol, also referred to as an "SAE") that is because of the administration of the Study drug in accordance with the Protocol. Sponsor shall not be responsible for the reimbursement of SAE costs that are the result of a) the negligence, misconduct, lack of adherence to applicable law or breach of this Agreement by any agent/vendor or employee of the Principal Investigator or Institution

9. DEBARMENT

9.1 Debarment and Exclusion. Institution and Principal Investigator 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. Institution and Principal Investigator also certify that they are not excluded from any governmental health care program. Institution and Principal Investigator 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 Institution will notify Veeda 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 Institution and/or Principal Investigator becomes aware of any material issues related to the medical licensure of any associated researchers. Institution and Principal Investigator will cooperate with Veeda and/or Sponsor regarding any responsive action necessary.

10. NOTICE

10.1 Notices. Except as otherwise provided herein, all notices, consents, or approvals required under this Agreement will be in writing delivered personally or delivered by facsimile, electronic mail, first class mail, or by a commercial overnight courier that guarantees next day delivery when possible (in the case of notice by facsimile or electronic mail, a confirmation shall thereafter be

transmitted to the addressee by first class mail or by a commercial overnight courier that guarantees next day delivery), addressed as follows:

If to Veeda:
Veeda Clinical Research Pvt. Ltd.
Address: Shivalik Plaza –A, 2nd floor, Nr. I.I.M., Ambawadi, Ahmedabad 380 015.
Attention: Dr. E. Venu Madhav
Phone: +91 79 30013000
Fax: +91 79 30013010

If to Principal Investigator:
Name: **Dr. Chandrashekhar Tamane**
Address: MGM Medical College & hospital, N-6 CIDCO, Aurangabad – 431003, Maharashtra

Attention:
Phone: +91- 9561707496
Fax: NA

If to Institution:
Name: Dr. A G Shroff
Designation: Dean
Address: MGM Medical College & hospital, N-6 CIDCO, Aurangabad – 431003, Maharashtra

Attention:
Phone: +91-240-6601100
Fax: +91-240-2487727

11. Miscellaneous

11.1 Binding Obligations. Principal Investigator and Institution represent and certify that the terms of this Agreement are valid and binding obligations are not inconsistent with any other contractual and/or legal obligations they may have, or with the policies of company with which it is associated.

11.2 Publicity. To the extent permitted by law or regulation, no party shall disclose the existence or terms of this Agreement nor use the name of any other party, nor the names of other party's employees, in any publicity, advertising or announcement without the consenting party's prior written approval.

11.3 Independent Contractor. Principal Investigator's and Institution's relationship to Veeda and Sponsor under this Agreement is that of an independent contractor, Principal Investigator and Institution have no authority to bind or act on behalf of Veeda or Sponsor.

11.4 Assignment. Principal Investigator and Institution may not assign this Agreement to any other party, nor may it subcontract any of its services hereunder, without Veeda's and Sponsor's prior written consent. Any attempted assignment without Veeda's and Sponsor's prior written consent shall be null and void and shall, for the avoidance of doubt, constitute a material breach of

this Agreement.

11.5 Sub-investigators. Principal Investigator and Institution hereby agree that as to any individuals identified on the applicable FDA Form 1572 or Investigator information and Agreement Form as sub-investigators for the Study, Principal Investigator and Institution shall ensure such individuals' compliance with the terms and conditions hereof.

11.6 Entire Agreement. This Agreement contains the entire understanding of the parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. This Agreement may be modified only by written agreement signed by the parties.

11.7 Governing Law. This agreement shall be governed by and interpreted in accordance with the Indian laws. Any disputes arising in connection with this Agreement shall be resolved through arbitration. The arbitrator shall be mutually decided among the parties. The arbitration shall be conducted under the Arbitration and Conciliation Act of 1996. The place of arbitration shall be Ahmedabad. Each party shall bear its own costs of the arbitration unless the arbitrator otherwise directs.

11.8 Survival. Notwithstanding termination of this Agreement for any reason, rights and obligations which by the terms of this Agreement survive termination thereof, shall remain in full force and effect including but not limited to Section 4 (Confidential Information), Section 5 (Intellectual Property) and Section 6 (Publication).

11.9 Severability. If any of the provisions or a portion of any provision, of this Agreement is held unenforceable or invalid by a court of competent jurisdiction, the validity and enforceability of the other portions of any such provision and/or the remaining provisions shall not be affected thereby.

11.10 Conflict with Protocol. In the event of a conflict between the terms and conditions of this Agreement and those of the Protocol, the Protocol shall control in matters of science and the Agreement shall control in all other matters.

11.11 Headings: Any headings, titles and captions used in this Agreement are for convenience and reference only. They do not purport to, and shall not be deemed to, limit or extend the scope or intent of the sections to which they pertain.

11.12 PI/Institute will be responsible for facilitating the availability of site level Phlebotomist dedicated for this study throughout the study duration.

MGM's Medical College Aurangabad

Vedic Clinical Research

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date written above.

For, Veeda Clinical Research Pvt. Ltd.

Name: Dr. E. Venu Madhav
Title: COO

Date: 12 Jan 2016

For, Principle Investigator

Name: Dr. Chandrashekhar Tamane
Title: Principle Investigator

Date: 01 Mar 2016

For, Institute

Name: Dr A G Shroff
Title: Dean, MGM Medical College, Aurangabad

Date: 01-03-2016

Witness:

Name: Dr Lunjamanshi Pravin.
Contact Details: 9764994449.

SCHEDULE "A"

PROTOCOL

TITLE:

"A randomized, multi center, open label, two-treatment, two-period, two-sequence, multiple dose, crossover, steady state bioequivalence study of Everolimus tablets, 10 mg of Biocon Limited, India vs. Afinitor® (Everolimus) tablets, 10 mg of Novartis Pharmaceuticals Corporation, USA in advanced renal cell carcinoma (RCC) patients."

SCHEDULE "B"

STUDY BUDGET

All defined terms shall have the same meaning attributed to them in the Agreement unless otherwise defined herein.

Institution/Principal Investigator will be paid based upon the number of Subjects properly enrolled and the visits completed by the Subjects as legibly, completely and accurately recorded in the CRFs.

Screen failure will be paid an amount of 5,000 INR respectively.

a) Trial Budget

Visit	Visit 1 (Screening)	Visit 2 (Day 0/1)	Visit 3 (Day 6±1)	Visit 4 (Day 11/12/13/14/15)	Visit 5 (Day 20±1)	Visit 6 (Day 25/26/27/28/29)	Sub-total
Study Team Grant							
Principal Investigator Grant	3,000.00	2,500.00	2,500.00	12,000.00	2,500.00	12,000.00	34,500.00
Study coordinator grant	1,000.00	1,000.00	1,000.00	5,000.00	1,000.00	5,000.00	14,000.00
Phlebotomy Charges*	200.00	200.00	-	2,000.00	-	2,000.00	4,400.00
Study Assessment Grant							
Urine Pregnancy Test and Urine Drug screen test	-	100.00		100.00		100.00	300.00
ECG	400.00	-				400.00	800.00
X-ray	350.00	-					350.00
Stationary, Phone, Courier and Fax charge	150	150	150	300	150	300	1,200.00
Hospitalization & Meal Charges	-	3,000.00		12,000.00		12,000.00	27,000.00
Sub-total	**5,100.00**	**6,950.00**	**3,650.00**	**31,400.00**	**3,650.00**	**31,800.00**	**82,550.00**
Institutional Overhead (20%)	**1,020.00**	**1,390.00**	**730.00**	**6,280.00**	**730.00**	**6,360.00**	**16,510.00**
Total							**99,060.00**
Service Tax (14%)							**13,868.40**
Total Grant							**112,928.40**
Patient Compensation	1,000.00	2,000.00	1,000.00	5,000.00	1,000.00	5,000.00	**15,000.00**
* Phlebotomy charges for PK sampling will be paid only if site phlebotomist is used.							

MGM's Medical College Aurangabad

Veda Clinical Research Ahmedabad

Taxes:

- All payments shall be made to the Principle Investigator / Institution / any other payee party as defined in the agreement, after deducting of withholding tax (TDS) as applicable from time to time as per the Income tax act. The TDS certificates for the withholding tax will be provided at the end of the financial year.

- Patient compensation will be treated as a reimbursement and TDS will be not deducted from the patient compensation subject to production of original bills and supporting documents (signed by patient) without any mark up by the Principle Investigator and Institution.