INDIA NON JUDICIAL

Government of Gujarat

Certificate of Stamp Duty

सत्यमेव जयते

Certificate No.	:	IN-GJ60142483618885S
Certificate Issued Date	:	13-Jan-2020 03:36 PM
Account Reference	:	IMPACC (FI)/ gjelimp10/ VAPI/ GJ-VL
Unique Doc. Reference	:	SUBIN-GJGJELIMP10608429068386666S
Purchased by	:	MERIL LIFE SCIENCES PVT LTD
Description of Document	:	Article 5(h) Agreement (not otherwise provided for)
Description	:	AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	MERIL LIFE SCIENCES PVT LTD
Second Party	:	MGM MEDICAL COLLEGE AND HOSPITAL DR S POLE
Stamp Duty Paid By	:	MERIL LIFE SCIENCES PVT LTD
Stamp Duty Amount(Rs.)	:	300 (Three Hundred only)

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MA 0002544758

CLINICAL TRIAL AGREEMENT

This Agreement (Hereinafter **"Agreement"**) is made and entered into on this **28th day of January 2020 by and among:**

Meril Life Sciences Pvt. Ltd., with its principal office located at **Bilakhia House, Survey No.135/139, Muktanand Marg, Chala, Vapi-396191, Gujarat, India represented by Dr. Ashok Thakkar, Head-Clinical Research.** [Hereinafter **"the SPONSOR"** or **"Meril"** (which expression shall unless it be repugnant to the context or meaning thereof be deemed to mean and include its successors and permitted assigns)**{FIRST PARTY}**

And

Mahatma Gandhi Mission Medical College & Hospital, with his principal office located at **Gate No. 2, CIDCO, Aurangabad, Maharashtra-431003, India** (Hereinafter "**Institution** or **Centre** or **Study Site**") represented by **Dr. Rajendra B. Bohra**, (Dean-Institute) having registered office at Gate No. 2, CIDCO, Aurangabad, Maharashtra-431003, India . [Hereinafter referred to as the "**Institution**" (which expression shall unless it be repugnant to the context or meaning thereof be deemed to mean and include its successors and permitted assigns)] of the **{SECOND PARTY}.**

And

Dr. Shivaji Pole with his principal office located at (Hereinafter "**Investigator**") **Mahatma Gandhi Mission Medical College & Hospital,** Sri Aurobindo Marg, Ansari Nagar, Ansari Nagar East, New Delhi, Delhi 110029.**{THIRD PARTY}**

And

Mr. Chandu Devanpally (Founder and Managing Director) with his principal office located at **SMO** of **Ardent Clinical Research Services** a private Site Management Organization having its address at Office No. 318, 3rd Floor, Next to Frankfin Institute, Connaught Place, Bund Garden Road, Pune - 411 001, Maharashtra, India **{FORTH PARTY}**

(Hereinafter individually "**Party**" or collectively "**Parties**")

WHEREAS the Sponsor is a Medical Devices company involved in research, development, manufacture and sale of medical devices for use in humans;

WHEREAS the Institute is recognized for its expertise and interest in Multispecialty Tertiary Care Hospital, and has the facilities, infrastructure and expertise to conduct the clinical study entitled:

Promesa™DES - 1: A Prospective, Multicenter, Single arm, Open label Study to Evaluate Safety and Performance of Promesa™ DES Sirolimus Eluting Self-Expandable Nitinol Peripheral Stent System for Treating Superficial Femoral Artery (SFA) and Iliac Artery Lesions.

(Hereinafter referred to as the "**Clinical Trial**" or "**Study**")

WHEREAS the Sponsor is desirous of conducting the Clinical Trial; and

1 Definitions

1.1 **"Affiliate"** means a business entity which controls, is controlled by, or is under the common control with the Sponsor or the Institute. For the purpose of this definition, a business entity shall be deemed to control another business entity if it owns, directly or indirectly, in excess of 50% of the voting interest in such business entity or the power to direct the management of such business entity.

1.2 **"Agent(s)"** shall include, but shall not be limited to, any person (including the Investigator, any nurse or other health professional), any such person's principal employer in the event it is not the Centre and where such person is providing services to the Centre under a contract for services or otherwise, and/or any contracted third party providing services to the Centre under a contract for services or otherwise for the Study.

1.3 **"Agreement"** means this agreement, any signed amendment to it, as well as any documents which are signed consequently in relation to the study including Protocol, exhibits, schedules, or other addendums attached and/or referred to in this Agreement. In case of discrepancy between the numbered Clauses of this Agreement and any addition to this Agreement such as exhibit, Protocol, etc., the numbered Clauses of this Agreement shall prevail.

1.4 **"Confidential Information"** includes, but is not limited to, any knowledge and information pertaining to a Party's products and processes, ingredients, recipes, know-how, product plans , business plans, management reports, financial statements, internal memorandum, reports, patient information, inventions, designs, drawings, methods, processes, systems, technology, technical information relating to the disclosing Party's research, improvements, materials, data, trade secrets, marketing and regulatory strategy, customer lists, supplier lists, database and any other information pertaining to the business of a Party, which is not readily available to the public and does not constitute Results.

1.5 **"Effective Date"** means the date of the latest to occur of the following two conditions:

(i) Signature of this Agreement by the last Party to sign and
(ii) Approval of the Study by the competent ethics committee, institutional review board or equivalent body.

1.6 **"Fee"** shall mean the fee payable by the Sponsor for performing the Study.

1.7 **"ICH GCP"** shall mean E6 (Applicable Revisions) guideline for Good Clinical Practise (GCP) issued by the International Council forHarmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) with applicable updates and amendments thereof.

1.8 **"Intellectual Property"** means any registered and unregistered intellectual property rights, such as, but not limited to, patents, designs, trademarks, trade names as well as copyrights, know-how, trade secrets and Confidential Information.

1.9 **"Lead Investigator"** means a physician chosen by Meril to provide scientific and medical supervision of the entire multi-centre Study.

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1.10 **"Investigator"** means the person designated by the Centre and agreed upon by Meril who will take primary responsibility for the conduct of the Clinical Trial at the Centre, or any other person as may be agreed from time to time among the Parties as a replacement.

1.11 **"Protocol"** means the Study protocol no. **MLS-Promesa™ DES-1** and all its amendments duly signed by the Investigator and the Sponsor.

1.12 **"Research Subject"** means any person recruited to participate in the Study as a patient.

1.13 **"Results"** means the contents and results of all work and activities realized by the Centre including the Agents pursuant to this Agreement, limited to results, clinical data and medical conclusions related to the treatment of the Research Subjects with the Study Device in accordance with the Protocol.

1.14 **"Study Device"** means **MLS-Promesa™ DES-1** as defined in the Protocol.

1.15 **"Study"** means the A Prospective, Multicenter, Single arm, Open label Study to Evaluate Safety and Performance of Promesa™ DES Sirolimus Eluting Self-Expandable Nitinol Peripheral Stent System for Treating Superficial Femoral Artery (SFA) and Iliac Artery Lesions.

1.16 **"Study Deliverables"** shall mean the completed case report forms, any electronic databases required to be created under the Protocol, and any Study reports prepared by the Institute for the Sponsor (including, with respect to the data contained in such case report forms, electronic databases, and reports, only the compilation of data or any substantially similar compilation).

1.17 **"Trial Monitor"** mean one or more persons appointed by the Sponsor to monitor compliance of the Clinical Trial with ICH GCP and to conduct source data verification.

2 Scope of the Agreement

Meril is sponsoring the Study entitled:
A Prospective, Multicenter, Single arm, Open label Study to Evaluate Safety and Performance of Promesa™ DES Sirolimus Eluting Self-Expandable Nitinol Peripheral Stent System for Treating Superficial Femoral Artery (SFA) and Iliac Artery Lesions.

2.1 Name of the study: **MLS-Promesa™ DES-1**

2.2 Meril shall act as the Sponsor of the Study, and the Centre shall act as one of the clinical sites at which the Study will be conducted. The Investigator has agreed to serve at the Centre as Principal Investigator in connection with the conduct of the Study. The Institute shall notify the Sponsor in advance if the Investigator is unable or unwilling to continue the Study or if the Investigator's affiliation with the Institute ceases, whereupon the Centre shall identify a successor whose appointment shall be subject to Meril's written approval.

2.3 The Investigator shall perform the Study in conformance with; (i) ICH-GCP guidelines, (ii) ISO 14155,(iii) Medical Device Directives of Global Harmonization Task Force and European Union,(iv) the Protocol, (v) all reasonable written instructions of the Sponsor and (v) all

applicable laws, rules and regulations (including, but not limited to the Indian Drug and Cosmetic Act 1940, the Indian Drug and Cosmetic Rules, 1945, any other guidance and notification issued by Central Drug Standard Control Organization (as may be amended from time to time).

2.4 The Institute/the Investigator shall seek approvals which may be required to carry out the Study, including approval from Ethics Committee (EC) or Institutional Review Board (IRB) or equivalent body as required by the applicable laws and applicable standards before commencing the Study.

2.5 The Institute shall comply with applicable laws in the collection, storage, and transfer of any clinical samples or other human materials taken from Study Subjects, and shall obtain any consents required from Study Subjects for the use of such materials in accordance with the Protocol. The Institute shall ensure that any use of such materials, whether in the Study or otherwise, shall be consistent with such consents and applicable laws.

2.6 The Institute shall ensure that the clinical samples or other human materials taken from Study Subjects are tested in accordance with the Protocol and at a laboratory designated by the Sponsor.

2.7 The Sponsor shall comply with applicable laws in the performance of its activities relating to the Study, and shall obtain all approvals and consents required in connection with such activities. The Sponsor shall conduct such Study-related activities in a manner consistent with the Informed Consents and all other applicable consents.

2.8 The Investigator shall ensure the study participation is voluntary and the participants have the right to withdraw at any time during the conduct of the study.

2.9 The Sponsor may amend the Protocol at any time. Any such amendment shall be in writing and sent to the Institute, and will not take effect until approved by the appropriate approving bodies such approval shall not be unreasonably withheld, conditioned or delayed.

2.10 Total 50 patients are to be enrolled in this study from across all sites in India and the centre shall enroll up to 10 eligible Research Subjects for participation in the Study.

2.11 The Centre shall collect Research Subject specific data as per the prescribed study schedule in the Protocol on Case Report Form (paper or electronic) (Hereinafter CRF) for the entire duration of the study. The Centre shall provide appropriate resources and facilities to enable the Investigator to conduct the Study in a timely and professional manner and according to the terms of this Agreement. The Centre shall ensure that only individuals who are appropriately trained and qualified will assist the conduct of the Study. The Centre is responsible for ensuring that all personnel of the Centre and Agents participating in the Study comply with the terms and conditions of this Agreement.

2.12 The Centre and the Investigator shall use their best endeavours to ensure that the recruitment of the Research Subjects is achieved in accordance with the timelines.
The Study being a multi-centre clinical trial, the Sponsor may amend the number of Research Subjects to be recruited at the Centre. If in the reasonable opinion of the Sponsor, recruitment at the Centre is proceeding at a rate below that required meeting the timeline, the Sponsor may, by

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a notice to the Centre, cease further recruitment. On the other hand, if the recruitment at the Centre is proceeding at a rate above that required meeting the timeline, the Sponsor may, with agreement of the Centre increase the number of the Research Subjects to be recruited.

2.13 Subject to the Centre's and the Investigator's overriding obligations in relation to the Research Subjects and individual patient care, neither the Centre nor the Investigator shall, during the term of this Agreement, conduct any other trial which might hinder the Centre's or Investigator's ability to recruit and study the required cohort of the Research Subjects.

2.14 Meril shall provide training to the personnel designated by the Centre for conducting the Study related activities. In addition, Meril shall conduct follow-up monitoring as it deems appropriate.

2.15 The details of activities of the Study (notably detailing scientific goals, methodology, and time schedule) are provided in the Protocol. The Centre and the Investigator shall not deviate from the Protocol except to the extent necessary for safety of the Research Subject/s and shall promptly notify the Sponsor and the EC/IRB in writing of any deviation from the Protocol with reasons.

2.16 The Institute shall refrain from, and shall cause the Investigator and the Agents to refrain from using the Study Device in any manner that is contrary to the provisions of, or outside the scope of, the Protocol or that is contrary to the written instructions of the Sponsor.

2.17 The decision to include any Research Subject in the Study shall occur only after the decision to use the Study Device on said Research Subject has been made exclusively on medical grounds by the Investigator. On enrolling the subjects in the study, the Centre shall complete the Electronic Case Report Forms (hereinafter "**eCRF**") for the Research Subject specific data as per the prescribed study schedule in the Protocol for the entire length of the Study. The Centre shall provide all necessary and sufficient facilities, equipment, resources and personnel to perform the services required hereunder.

2.18 The Institute and the Investigator shall supervise Agents employed by the Institute for conduct of the Study (the Study Staff), and shall ensure (directly in the case of employees, and by contract in the case of contractors) that all Study Staff are appropriately trained, qualified, and certified, and are informed of and abide by the applicable terms of this Agreement.

2.19 The Institute shall keep and maintain, diligently and in sufficient detail to satisfy all applicable legal requirements, such Study data and records as are required by the Protocol and applicable laws, including any source data, clinical data of Research Subjects and Study Deliverables (the "Study Documents").At the Sponsor's request, the Institute shall retain the Study Documents beyond the period required by the applicable laws Study Documents in accordance with applicable laws. After the required retention period (including any additional period requested by the Sponsor) has expired, the Institute shall provide the Sponsor sixty (60) days' written notice before destroying any Study Documents.

2.20 In order for Meril to monitor the progress of the Study, a regular exchange of letters, emails and phone calls between Meril and the Investigator shall occur during the performance of the Study. Face-to-face meetings may also be held between Meril and the Investigator as often as

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reasonably necessary. The Institute and the Investigator will allow, with reasonable prior notice, Meril and /or the regulatory authorities to perform facility and site audit.

2.21 The Institute shall permit the Trial Monitor to access the Study Documents during regular business hours, upon reasonable advance notice to the Institute by the Sponsor. The Sponsor shall comply with applicable laws regarding the confidentiality of Study Subjects' medical records and other health information, shall hold the Study Subjects' personal identifying information in confidence, and shall act in accordance with the Informed Consents and the HIPAA Authorizations. Subject to the foregoing, the Trial Monitor may copy Institute records containing such information. The Institute may redact personal identifying information of Study Subjects before giving them to the Study Monitor for copying these records. The Sponsor shall not attempt to contact any Study Subject except to the extent expressly permitted by the IRB or as required to comply with applicable laws.

2.22 During monitoring as per Clause 2.19, the Trial Monitor has the right to inspect any facility being used for the Study and to examine any procedures or records relating to the Study. The Trial Monitor/Sponsor will alert the Centre and the Investigator to significant issues (in the opinion of the Trial Monitor/Sponsor) relating to the conduct of the Study.

2.23 The sponsor's monitor to send the post-monitoring visit report promptly to the site.

2.24 In the event that the Sponsor reasonably believes there has been any research misconduct in relation to the Clinical Trial, the Centre and the Investigator shall provide all reasonable assistance to any investigation into any alleged research misconduct undertaken by or on behalf of the Sponsor. The Sponsor shall, subject to any obligations of confidentiality, communicate the results of such investigation to the Centre. In the event that the Centre reasonably believes there has been any research misconduct in relation to the Clinical Trial, the Sponsor shall provide all reasonable assistance to any investigation into any alleged research misconduct undertaken by or on behalf of the Centre, the results of which shall, subject to any obligations of confidentiality, be communicated to the Sponsor.

2.25 The Institute shall make available to the Sponsor or its designated agent the Study site, the Study Staff, and, subject to applicable laws relating to patient confidentiality, all Study Documents for purposes of review and audit upon reasonable advance notice during regular business hours. If the Investigator fails to correct any violations of the Protocol, this Agreement, or applicable laws found in such audit after receiving written notice thereof, the Sponsor may provide notice to the Institute of such violations, whereupon the Institute shall promptly take action to correct them.

2.26 The Institute shall provide the Sponsor prompt, advance notification of any audit by a regulatory authority, which audit is directly related to the Study (or, when advance notification is impracticable, prompt notification of any completed audit). To the extent possible, the Institute shall permit the Sponsor to review and comment in advance on any written communication from the Institute to the regulatory authority in connection with such an audit; provided, however, that such review does not adversely impact the timeliness of the Institute's response to the regulatory authority. The Institute shall promptly provide the Sponsor with copies of all communications between the Institute and the regulatory authority related to such audit unless prohibited from so doing by the regulatory authority, and shall promptly take action to correct any deficiencies found by the regulatory authority during the audit. With respect to a pending audit directly

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related to the Study by any regulatory authority, the Institute shall permit the Sponsor's representatives to be present at such audit unless prohibited from so doing by regulatory authority. With respect to any audit by any regulatory authority, which audit is not directly related to the Study, the Institute shall promptly notify the Sponsor of any findings of such an audit that would be likely to have an adverse effect on the Institute's ability to conduct the Study.

2.27 The sponsor to send the DSMB report if applicable and its timely submission to Ethics Committee.

2.28 The Sponsor shall reimburse actual and reasonable medical expenses incurred in treating any injury or illness to a Study Subject that is directly related to the conduct of the Study in accordance with the Protocol and the Sponsor's written instructions to the Institute (or to the extent that the Sponsor's written instructions conflict with the Protocol, the Sponsor's written instructions to the Institute only). The Sponsor is not required under this Section 2.26 to provide compensation for (a) other injury- or illness-related costs (such as lost wages), (b) medical expenses that are paid for by a third party (provided that neither the Institute nor the Study Subject shall be obligated to seek reimbursement from a third party insurer), (c) medical expenses that are incurred as the result of a violation of the Protocol or other misconduct or negligence, in each case by any Agent of the Institute (including the Study Staff and the Investigator), or (d) medical expenses for injury or illness unrelated to the Study Device and unrelated to the proper performance of any other procedure required by the Protocol or Sponsor's written instructions to the Institute. The Sponsor confirms that it has taken appropriate insurance policy for the conduct of the Study as per the applicable laws.

3 Confidentiality

3.1 The Centre and the Investigator agree that any Confidential Information (or any evaluation thereof including but not limited to analysis, deconstruction, disassembling or reverse engineering) received from Meril shall be held in strict confidence and centre shall not disclose or use (other than in connection with or expressly permitted by this Agreement). All Confidential Information shall remain the property of Meril. Such information shall be used by the Centre and its Agents including the Investigator only in the performance of their duties hereunder, and shall not be used or disclosed, directly or indirectly to any third party, except as necessary to accomplish the purposes of this Agreement and then only if such Agents, and third party/parties are bound by an obligation of confidentiality consistent with the terms of this Agreement or as required by the law. The Centre hereby assures that their Agents including, but not limited to, the Investigator shall comply the provisions of this Clause. Upon the request of Meril, the Centre shall promptly return to Meril all Confidential Information of Meril in the possession of the Centre, the Investigator or other personnel and Agents, together with any documents or notes containing such Confidential Information, except for one archival copy which may be retained by the Centre if required in order to monitor compliance with the terms of this Agreement and the applicable laws.

3.2 The Centre, the Investigator, or any other personnel of the Centre, or Agents shall not publicly or privately disclose or divulge any term or provision of this Agreement or the transactions contemplated hereby without the prior written consent of Meril, except as may be required by applicable law, rule, regulation or order and the internal reporting requirements of the Centre, and

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12.7 **Force Majeure.** Noncompliance by a Party with this Agreement due to any cause beyond the reasonable control of the Party, such as war, civil commotion, destruction of production facilities and materials, fire, flood, earthquake or storm, labor disturbances, shortage of materials, failure of public utilities or common carriers (each, an event of "Force Majeure"), shall not constitute a breach of this Agreement. That Party shall be excused from performance under this Agreement to the extent and for the duration of such event of Force Majeure; provided, however, that it first notifies the other Party in writing thereof and that it uses reasonable efforts to cause such event of Force Majeure to abate.

12.8 **Governing Law/Jurisdiction.** This Agreement shall be construed and interpreted in accordance with the laws of India, without regard to its conflict of law's provisions. Any action brought to enforce or interpret this Agreement shall be brought in the courts of Mumbai subject to appeal in the higher courts in India, and each Party hereby consents to the jurisdiction thereof.

12.9 **Severability.** If any term or provision of this Agreement is held to be invalid, unenforceable, or void by a court of competent jurisdiction, the remaining terms and provisions shall nevertheless be enforceable according to their terms.

12.10 **Counterparts.** This Agreement may be executed in one or more counterparts, which taken together, shall constitute one and the same instrument.

12.11 **Interpretation.** Unless the context of this Agreement requires otherwise, words of one gender include the other gender; words using the singular or plural number also include the plural or singular number, respectively; the terms "Clause" and "Section" refer to the specified Clause and Section of this Agreement; and the term "including" means "including, without limitation."

12.12 **Notices.** The Parties shall send notices in writing, referencing this Agreement. Notice shall be deemed given: (a) when delivered personally; (b) one (1) day after having been sent by facsimile, with a copy sent promptly by registered or certified mail, return receipt requested, postage prepaid; (c) by e-mail with a copy sent promptly by registered or certified mail, return receipt requested, postage prepaid; five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid; or (d) two (2) days after deposit with a nationally recognized overnight carrier, with written verification of receipt. Notice shall be given to the addressee below ;

To the Institute: **Mahatma Gandhi Mission Medical College & Hospital,**
Gate No. 2, CIDCO, Aurangabad, Maharashtra-431003, India
Attention: Dr. Rajendra B. Bohra
(Dean-Institute)
E-mail: mgmmca@themgmgroup.com

With a copy to: **The Principal Investigator**
Name: Dr. Shivaji Pole
E-mail: drsmp111@gmail.com
Fax: NA

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To the Sponsor:

Meril Life Sciences Pvt. Ltd.
Bilakhia House, Survey No. 135/139
Muktanand Marg, Chala, Vapi-396191
Gujrat, India.
Attention: Dr. Ashok Thakkar
E-mail: ashok.thakkar@merillife.com

IN WITNESS WHEREOF, the parties have duly executed this agreement as of the date first written above.

Sponsor: Meril Life Sciences Pvt. Ltd.

Signature:

Date: 29/Jan/2020

MERIL LIFE SCIENCES PVT. LTD.

Print Name: **Dr. Ashok Thakkar**

Title: **Head - Clinical Research and Medical Writing**

Address for Notices: Bilakhia House, Survey No. 135/139, Muktanand Marg, Chala, Vapi-396191 Gujarat, India.

Institution: Mahatma Gandhi Mission Medical College & Hospital,

Signature:

Date: 21-Feb-2020

Dean
MGM Medical College,
Aurangabad.

Print Name: **Dr. Rajendra B. Bohra**

Title: **Dean**

Address: Mahatma Gandhi Mission Medical College & Hospital, Gate No. 2, CIDCO, Aurangabad, Maharashtra-431003, India

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Investigator: Dr. Shivaji Pole

Signature:

Date: 20/Feb/2020

Dr. Shivaji M. Pole
MBBS, MD (RAD), Fellow in
Vascular Interventional Radiology
EM [illegible]
Asst Prof & Chief Interventional
Radiologist
MGM Superspeciality Hospit
Aurangabad
Reg No 2005/03/1

Print Name: Dr. Shivaji Pole

Title: **Principal Investigator**

Address: Mahatma Gandhi Mission Medical College & Hospital, Mahatma Gandhi Mission Medical College & Hospital, Gate No. 2, CIDCO, Aurangabad, Maharashtra-431003, India

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Site Management Organization(SMO): Ardent Clinical Research Services

Signature:

Date: 03/Feb/2020

Print Name: **Mr. Chandu Devanpally**

Title: **Founder and Managing Director**

Address: Office No. 318, 3rd Floor, Next to Frankfin Institute, Connaught Place, Bund Garden Road, Pune - 411 001, Maharashtra, India

EXHIBIT-A

Meril shall pay to the Payee (as per Clause 7 of the Agreement) following Fee subject to and in compliance with the terms and conditions of this Agreement. Total 50,450/- INR (Fifty thousand four hundred fifty Indian National Rupees) for each Research Subject will be paid Mahatma Gandhi Mission college & Hospital based on submission of the data in compliance with the terms and conditions of this Agreement. The schedule of payment will be as given in the following table.

A-Lab Investigation Charges

	Baseline/Index Procedure	Post Procedure	1 Month	6 Month	12 Month	24 Month
Angiography	NA	NA	NA	*	NA	NA
ECG	300	NA	NA	NA	NA	NA
Ankle Brachial Index & Rutherford Index	500	NA	500	500	500	500
Doppler Ultrasonography	2000	-	-	2000	2000	2000
Lab Measurements	1000	NA	NA	NA	NA	NA
UPT	150	NA	NA	NA	NA	NA
Total Cost	**3950**	NA	**500**	**2500**	**2500**	**2500**

Total: INR 11,950

B-Per Patient Grant

	Baseline/Index Procedure	Post Procedure	1 Month	6 Month	12 Month	24 Month
Including Investigator Charges & site Expanse	9000	-	5000	4000	4000	4000
study coordinator charges	1200	-	900	900	900	900
Total cost	10200	0	5900	4900	4900	4900
IOH @ 25%	2550	0	1475	1225	1225	1225
Total cost	28750	0	3375	2125	2125	2125

Total- 38,500

Total cost per subject (A+B)= 50,450

*Optional and performed only when necessary

1. Patient Travel Reimbursement: Patient will be reimbursed for actual expenses incurred maximum up-to 1000 INR for travel at scheduled clinical visits

2. Reimbursement of any additional pass through cost including optional cost shall be subject to sponsor's prior approval.

3. Study Device is free of cost to subjects but any additional hardware, medicine and procedure cost will be borne by the subject only.

4. At 6 month follow-up, if angiography is performed; sponsor will pay on the basis of actual invoice/bill.

5. If ECG will be performed at post procedure, 1month, 6 month, 12 month, 24 month, sponsor will pay on the basis of actual invoice/bill.

6. Laboratory & Radiology Investigations on an actual, however, TDS will be applicable in case the laboratory used is of the same Institution.

7. TDS and GST, as applicable.

8. Meril will provide TDS Certificate on quarterly basis which can be claimed by the hospital while filing its ITR.

9. If the lab bills are from 3rd party vendor then in that case TDS will not be deducted.

Also, if travel tickets are not available for 'Subject Reimbursement' then TDS will be deducted.

10. If we receive vouchers from site and in travel if it is mentioned as bus ticket or train ticket, then ticket should be provided. Else TDS will be deducted.

- If subject travel from auto then also it should be mentioned in voucher and the amount should be justifiable.

11. After the study close out at the site, study related documents will be archived at the central archival facilities by third party vendor.