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CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (the "Agreement") is entered into as of this day of (the "Effective Date"), by **AXIS Clinicals Ltd having registered office situated at 1-121/1, Miyapur, Hyderabad 500049**, [hereinafter referred as **"AXIS"**] acting as an independent contractor for **(Belupo Pharmaceuticals and Cosmetics, Incorporated)** a company with offices located **c/o (Ulica Danica 5, 48 000 Koprivnica, Croatia, Phone: +385 1 2481 214, Fax: +385 1 2481 290)** Hereinafter referred as **"Sponsor"**]

And

Dr. Kishan Ninama [hereinafter referred to as **"*Principal Investigator*"**] employee/ affiliate of **Sumandeep Vidyapeeth an Institution Deemed to be University & Dhiraj Hospital, [hereinafter referred to as "*Institution or Site*"] located at (Sumandeep Vidyapeeth, At & Po. Piparia, Ta. Waghodia, Dist Vadodara 391760).**

And

(Sumandeep Vidyapeeth an Institution Deemed to be University) whose principal place of business is, **Sumandeep Vidyapeeth, At & Po Piparia, Ta. Waghodia, Dist Vadodara 391760, Gujarat India, represented by Dr Chandramani More).**

(Hereinafter referred to as the **"Institution"** which expression, unless repugnant to the subject or context therein, shall mean and include its authorized representative(s), administrators, executors, assigns & successors-in-interest).

WHEREAS, the Site has personnel and facilities for carrying out the (A multicentre, double-blind, randomized, single-period, placebo-controlled, parallel group study of Adapalene 0.1% and Benzoyl Peroxide 2.5% Topical Gel of BELUPO Inc., Croatia (Test) and Epiduo Gel (Adapalene 0.1% and Benzoyl Peroxide 2.5%) (Reference) of Galderma (EU) in subjects with mild to moderate facial acne vulgaris).

WHEREAS **Sponsor** is desirous of engaging the said Site for carrying out the Study through **AXIS CLINICAL LTD,** acting on behalf of and as authorized representative and agent of **(Belupo Pharmaceuticals and Cosmetics, Incorporated)**

NOW, THEREFORE, in consideration of the premises and the covenants and agreements of the parties as hereinafter set forth, the parties have agreed and do hereby agree with each other to the following:

DEFINITIONS

"Study" means the clinical study of the test for the SPONSOR conducted through and under control of AXIS and conducted at Site as specifically identified in this Agreement.

"SPONSOR'S Confidential Information" means all information (including, without limitation, study protocols, case report forms, clinical data, other data, reports, specifications, computer programs or models and related documentation, know-how, trade secrets, or business or research plans) of **SPONSOR or SPONSOR's** Affiliates that are: (1) provided to Sites in connection with this Agreement or the Study; (2) Study data, results, or reports created by Institution, Investigation, or Study Staff in connection with the Study (except for a Study Patient's medical records); and (3) cumulative Study data, results, and reports generated from all sites conducting the Study.

Attested CTC

"Investigator/s" means the individual(s) responsible for the conduct of the Study at Site and for direct supervision of Study Staff.

30/11/2023

Vice-Chancellor
Sumandeep Vidyapeeth
An Institution Deemed to be University
Vill. Piparia, Taluka: Waghodia.
Dist. Vadodara-391 760. (Gujarat)

SUMANDEEP VIDYAPEETH

28/11/19

"Study Staff" mean the individuals providing services on behalf of Site with respect to the Study at Site, including without limitation sub-investigator, study coordinator, and other Site employees, agents, or subcontractor.

"Invention" means any discovery, development, invention (whether patentable or not), improvement, work of authorship, formula, process, composition of matter, formulation, method of use or delivery, specification, computer program or model and related documentation, know-how or trade secret, that is made by Institution, Investigator, or Study Staff: (1) in connection with the Study; or (2) which incorporate **SPONSOR** Confidential Information.

"Study Timelines" means the Enrollment date, End Date, the Visits Completed Date and the CRF Target Date set out in Section 1 of this Agreement.

"Study Supplies" means Study drug(s) and related devices, equipment (if required), or other trial supplies provided by AXIS/-Sponsor for the conduct of the Study.

"Protocol" means the written document that describes the Study and sets forth specific activities to be performed as part of Study conduct.

"eCRF or Electronic Case Report Form" means a printed, optical, or electronic document designed to record all of the protocol required information to be documented and reported on each patient.

"Test/Investigation study" means (A multicentre, double-blind, randomized, single-period, placebo-controlled, parallel group study of Adapalene 0.1% and Benzoyl Peroxide 2.5% Topical Gel of BELUPO Inc., Croatia (Test) and Epiduo Gel (Adapalene 0.1% and Benzoyl Peroxide 2.5%) (Reference) of Galderma (EU) in subjects with mild to moderate facial acne vulgaris)

"Data" shall mean all information, reports, records, and document provided and /or generated under this agreement excluding patient hospital medical records (case sheets). Data shall be the sole and exclusive property of **Sponsor.**

1. STATEMENT OF WORK

The Site has study staff, other personnel and facilities for carrying out the Study in strict compliance with any and all applicable Central, State, and Local laws, Regulations and Guidelines, Good Clinical Practices, all requirements of the host institution or facility, and any other relevant professional standards, and specifically to conduct the Study in accordance with the 'Undertaking by the Investigator' and Protocol, which Principal Investigator has read, gone through in detail, discussed with AXIS signed, and delivered to AXIS prior to the commencement of the Study at the Site.

The Principal Investigator shall use his or her best efforts to recruit only qualified participants as per Inclusion and Exclusion criteria and shall not knowingly enroll any participants, which in his or her best professional judgment do not adequately meet the criteria for qualified participants.

The following plan will apply to the Study:

(1) Site acknowledges that Site's minimum enrollment goal is 25 Patient with facial acne vulgaris. The timeline is 3 months from the date of Site Initiation. Site will use its best efforts to reach the enrollment goal. If Site fails to adhere to such enrollment goal and failed to start enrollment within 30 days of Site Initiation, AXIS may reconsider Site's suitability to continue participation in the Study or may change its enrolment goal or do the pre-closure of the site.
(2) Institution or Investigator may enroll more study patients than Institution's allotted Enrollment number after having a written communication with AXIS and after mutual agreement between both the parties.

(3) Investigator is responsible for obtaining from all subjects informed consents prior to screening for, or participation in the Study. All informed consents must be in the form approved by CRO and Sponsor, comply with the requirements of all Applicable Laws, and have been reviewed and approved by applicable regulatory authorities and Institutional Review Boards ("IRBs") or Independent Ethics Committees ("IECs").

(4) Source Documents, electronic Case Report Forms ("e-CRFs") and other information associated with a patient's visit must be satisfactorily completed after the patient's visit or, if applicable, receipt of the patient's test results.

(5) Investigator will provide the name of any SMO he has been contracted for the site activities either directly with Investigator or Site .

(6) Investigator will provide the contract between the site and SMO for AXIS reference after masking the confidential details .

(7) Investigator should provide the name of one dedicated and one back up CRC for the study during site initiation .

(8) Investigator is totally responsible for the activities as mentioned in the CTA . It will be the investigator responsibilities to monitor the work of any SMO/CRC appointed by him only .

(9) All data Queries from SPONSOR/AXIS must be clarified completed and responded to AXIS/SPONSOR within a time frame acceptable with AXIS/sponsor.

(10) Any intentional changes of inclusion/exclusion criteria by the Principal Investigator or study team will not be the liability of AXIS.

(11) Investigator or Institute agrees to cooperate with the representatives of CRO and Sponsor who visit Study Site, and Site agrees to ensure that Site Personnel does not harass, or otherwise creates a hostile working environment for such representatives

(12) Investigator may not be removed or replaced without prior written confirmation from AXIS and Sponsor. If Investigator is unable or unwilling to continue the Study or terminates his or her employment relationship with Institution, Institution shall immediately notify CRO and Sponsor in writing, and shall use all reasonable efforts to find a suitable replacement investigator acceptable to Sponsor and this Agreement will be amended accordingly. If Institution is unable to replace Investigator to Sponsor 's reasonable satisfaction promptly, AXIS/Sponsor shall have the right to terminate this Agreement/site.

(13) Site personnel/s who has ever been debarred, disqualified or banned from conducting clinical trials or is under investigation by any regulatory authority for debarment, disqualification, or any other similar regulatory action in any country will not be the part of the study. Site shall notify CRO immediately if any such investigation, disqualification, debarment, or ban comes to the attention of Site during the course of the Study.

AXIS/ SPONSOR will provide Principal Investigator with a sufficient quantity of study supplies to conduct the study at investigational site as per the study requirement in timely manner. Site shall use study supplies only to conduct the Study in accordance with the Protocol; shall not chemically, physically or otherwise modify Supplies,; and shall handle, store, and ship or dispose of Supplies in compliance with all applicable Local, State and Federal laws, rules and regulations including, but not limited to, those governing hazardous substances. Institution and Investigator will not charge any payment to Study patient or third-party to pay for any Supplies, or for Study procedures for which payment by AXIS has or will be made under this Agreement. All study supplies such as Study drug(s) and related devices, equipment, or other trial supplies remain the sole property of SPONSOR/AXIS, unless otherwise designated. The Institution and Principal Investigator will be responsible for the return of excess, unused study supplies to the SPONSOR/ AXIS.

2. PAYMENT

In consideration for conducting the Study, AXIS shall pay Site as described in Exhibit A. The parties agree that these payment terms are consistent with the principles of fair market value payments for the performance of Study-related activities. All of AXIS's payment obligations are conditioned upon Site's compliance with standards identified in this Agreement. AXIS will not make payments, or, if payment has been made by AXIS, Site will repay to AXIS any payments, for study visits, procedures, or other work associated with a Study patient if AXIS determines that the patient's data is not evaluable because of a violation of the Protocol by Investigator or Study Staff.

Payment will be released within 30 days from the date of receipt of two copies of original invoices duly signed by the authorized and printed on letter head of the Institution with seal/stamp as per format provided by Axis Clinicals Ltd.

Investigator and Institution agree that their judgment with respect to the advice and care of each subject will not be affected by the payment they receive from this Agreement, that such payment does not exceed the fair market value of the services they are providing, and that no payments are being provided to them for the purpose of inducing them to purchase or prescribe any drugs, devices or products. If Sponsor or CRO provides any free products or items for use in the Study, Site agrees that they will not bill any subject, insurer or governmental agency, or any other third party, for such free products or items or for any visits, services or expenses incurred during the Study for which it has received payment from CRO or Sponsor, or which are not part of the ordinary care they would normally provide for the subject

AXIS shall pay on per patient basis and per visit completion for each Satisfactorily Completed Patient (as defined below) in accordance with Exhibit -A.

"Satisfactorily Completed patient" shall be one in which a patient is a Qualified Participant (as per inclusion/exclusion criteria), has completed the specified Study period, and has been evaluated in accordance with the Protocol. If a Patient is discontinued for reasons stipulated in the Protocol, the Site shall be paid a prorated rate for extent of participation as per actual completed visits according to the applicable value mentioned in the exhibits.

Per Patient Costs: Payments will be made on a per visit/day basis for visits/days completed, in accordance with Exhibit -A. The estimated total amount per patient listed in the Per Patient Budget is calculated for a patient that completes all the study visits. Screening visit will be paid for consented patients for whom all screening procedures are performed. All visit costs include institutional overhead, staff fees and applicable taxes.

A completed and evaluable patient defined as:

- All procedures must be performed and bound to be completed according to protocol
- A patient will only be included according to inclusion and exclusion criteria
- All data documented accurately and completely
- All data queries completed
- All source, eCRF and other study related documents completed as per good documentation practices / AXIS standard requirements. No document will be considered acceptable if AXIS requirements are not complied with for completed and evaluable patient.

The per patient **costs 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 visit assessment and eCRF completion
- Time and efforts of Principal Investigator/s and other Site personnel
- All manpower cost who are involved in the study conduct
- Housing or hospital stay for patients including meals
- patient reimbursement/ Compensation
- All overhead costs of Institutions.
- Usage of Instruments/ equipment's which during the study should be having for proper instrument ID, maintenance and calibration certificate/ Annual Maintenance Contract
- Miscellaneous (telephone, fax, courier, storage cupboards and maintenance of Site infrastructure)

Screen Failures/ Drop-outs: A maximum of three (03) patients' total enrollment per site will allowed for, for Screen failures for drop-outs payment will be made on a prorated basis for the number of completed visits. This amount will be paid at the time of final payment.

Set-Up Fees: AXIS will pay to the PI/Institute an upfront initial advance amount of INR 1,00,000/- at least 15 days before initiation of the study after successfully obtaining the approval from Institution Ethics Committee & Drug controller General of India. This up-front advance payment would be deducted/ adjusted on pro-rata basis from further subsequent payments. In case the site is unable to enroll any patients, the PI/Institute will refund the site set up fees along with the TDS amount deducted (INR 90,000/- [Original] + INR 10,000/- [TDS] to AXIS Clinicals Limited by online mode of payment/cheque in the name of AXIS Clinicals Limited within a period of 30days from the last date to enrollment or any other dates as mutually decided by the parties. AXIS Clinicals will also provide the confirmation in writing for the deduction of TDS if requested by the Site and will provide Form-16A at the end of current financial year.

Additional Testing, Treatment or Procedures: Reimbursement will not be made for any additional testing, treatment, or procedures not required by the Protocol, unless such additional testing, treatment or procedures are pre-approved by AXIS/ Sponsor in writing.

Patient Travel Reimbursement: Subject Travel reimbursement will be done as per the details mentioned in Exhibit A. AXIS will release the funds to Site for each subject, i.e., **(INR 2500 /-)** (Rupees two thousand five hundred only) on successful completion of study. However, it will be the obligation of Principal Investigator to pay the subject reimbursement on a pro rata basis as defined in Exhibit A from the site set up fees. A receipt will be provided by the Institution for amount paid to subject in a specified format supplied by AXIS/Sponsor on the letterhead of the Institution or as per the institutional practice. However the original receipts of patient reimbursement should be provided along with the invoice for payment release.

Hospitalization costs: Apart from study specific in-house, per actual, in the event of any Serious Adverse Event (SAE) will be reimbursed.

EC Fees: EC fees will be reimbursed as per the actuals.

Payee name	Research Cell Sumandeep Vidyapeeth
Account Number	178802000000131
Bank Name	Indian Overseas Bank
Branch Name	Piparia
Swift/IFSC Code	IOBA0001788
PAN Number	AAATK4485H
GST No	24AAATK4485H1ZK

EC should provide a copy of PAN Card and Cancelled cheque

Site Payments shall be directed as follows:

Payee Name (Account name)	Research Cell Sumandeep Vidyapeeth
Account Number	178802000000131
Bank Name	Indian Overseas Bank
Branch Name	Piparia
Swift/IFSC Code	IOBA0001788
PAN Number*	AAATK4485H
Send to	Research Cell Sumandeep Vidyapeeth
#GST No:	24AAATK4485H1ZK

* Payee/s should provide a copy of PAN Card and cancelled cheque.

GST will be paid @ 18 % and the TDS will be deducted on actuals if applicable.

Any ancillary supportive treatment for safety of patient as agreed upon by AXIS/ Sponsor.
In case of Govt. of India will implement any other Tax regimen, the same will be implemented in due course of time with amendment/ Addendum of CTA.

(Sumandeep Vidyapeeth an Institution Deemed to be University & Dhiraj Hospital), will raise Invoice as per the statutory requirement for completed visits according to actual work performed (Number of Visits/cycles completed in the study site, eCRF completion, source data verification and eCRF review for completed visits) as per the criteria mentioned in the definition of "A Completed and evaluable patients" mentioned in Page no -4 . Advance paid will be adjusted against the first invoice and subsequent invoice payments in a mutually agreed manner.

In the event there is a refund due to AXIS at the time of premature termination by either party, the Principal Investigator agrees to remit the same to AXIS within fifteen (15) days of the date of effective termination.

Last 3 patient of the site payments will be on hold till Site Close out visit and will be released by the successful completion of the documentation, all instruments should be returned and other activities by site people.

Tax deduction: All fees and amounts except patient reimbursement and otherwise specifically listed are inclusive of applicable tax (TDS- Tax Deduction at Source). Prevailing TDS rate will be deducted from each payment disbursed to the institution for the study as per the applicable existing tax laws in the country. Certificate for the tax deducted at source will be provided at the end of the financial year.

In case the any other tests/analysis charges as per the protocol **(Sumandeep Vidyapeeth an Institution Deemed to be University & Dhiraj Hospital)** and in designated In-House labs, diagnostic centers, then TDS amount will be deducted as per the applicable requirement. All the payments will be done against the invoice/s that has been generated from sites in the name of AXIS Clinicals Limited. If the site outsourced the same to other laboratories or organization and will submit the original bill of the same activity from that institution, in that case TDS will not be deducted.

3. ETHICS COMMITTEE APPROVAL

The Principal investigator shall be responsible for obtaining approval of the protocol, related study documents and study conduct at the Site before initiation of the study.

Site also represents and warrants that EC registration and re-registration with Central Drug Standard Control Organization (CDSCO) and they have obtained and will maintain the required authorization from the Ethics Committee and any other required forms fully complying with the applicable regulations.

4. PROPRIETARY INFORMATION AND CONFIDENTIALITY

Sponsor shall have sole ownership of intellectual property developed in the Study by Investigators supported through Study funds. The Site shall disclose to AXIS/SPONSOR all inventions and other creative ideas and developments conceived or reduced to practice as a direct result of this Study. Such disclosure shall be made fully and promptly in writing to AXIS. All documents, data, know-how, formulas ("Data"), and unused drug provided to the Site for purposes of the Study are and will remain Sponsor's property and will be returned to Sponsor or their designate upon request.

SPONSOR/AXIS Confidential Information and all tangible expressions, in any media, of SPONSOR/AXIS Confidential Information are the sole property of SPONSOR/AXIS.

Institution agrees not to use SPONSOR/AXIS Confidential Information for any purposes other than to conduct the Study. Institution agrees not to disclose SPONSOR/AXIS Confidential Information to third parties except as necessary to conduct the Study and under an agreement by the third party to be bound by the obligations of this Section. Institution shall safeguard SPONSOR/AXIS Confidential Information with

the same standard of care that is used with Institution's Confidential Information, but in no event less than reasonable care.

The obligation of non-disclosure and non-use shall not apply to the following.

(1) Information, which at the time of disclosure hereunder, is generally available to the public;
(2) Information, which after disclosure hereunder, becomes generally available to the public, except through breach of this Agreement;
(3) Information that the Institution can demonstrate was in its possession at the time of disclosure by Sponsor and that was not acquired, directly or indirectly, from Sponsor;
(4) Information that becomes available to the Institution from a third party that is not legally prohibited from disclosing such information, provided such information was not acquired directly or indirectly from Sponsor; or
(5) Information that is required by law to be disclosed to representatives of a Governmental Agency and to which they are entitled when engaged in the proper performance of their duties.

The Investigator agrees to keep all aspects of the trial confidential. This includes the nature of the trial, the protocol and its attached forms as well as data generated by the trial.

The obligations of this Section shall survive till the termination of this Agreement.

5. HANDLING INVESTIGATIONAL PRODUCTS

The Investigator agrees to exercise adequate care in the application and handling of Investigational products.

Site shall use the drug, device, product or compound being tested (the "investigational Product"), and any comparator products provided in connection with the Study solely for the purpose of properly completing the Study according to the Protocol, the Agreement, and Applicable Laws. Site shall take reasonable measures to protect the investigational Product and any comparator products from loss or damage, including storing them in a locked, always secured area according to the Protocol, IMP manual/s and Applicable Laws. Site acknowledges that the investigational Product and any drugs and comparator products always remain exclusive properties of Sponsor. Upon completion or termination of the Study or at such times as Sponsor or AXIS may direct, Site shall return all unused investigational Product, containers for investigational Products (even if used), comparator products, and any other equipment, and materials provided by SPONSOR or AXIS, in accordance with the instructions provided by SPONSOR or AXIS.

6. SERIOUS ADVERSE EVENT REPORTING

The Principal Investigator shall fully comply with adverse event assessment and reporting criteria as per the provisions of the Protocol. In the event of any omission of such provisions or in the event of the conflict of such provisions with the Regulations, then the Regulations shall apply in relation thereto.

The Principal Investigator shall also notify the IEC/Central licensing authority/Sponsor immediately of any Serious Adverse Events during the Study in accordance with the current existing regulations.

In the event of SAE injury, patients will be provided free Medical management as long as required by **Belupo Pharmaceuticals and Cosmetics, Incorporated** a company with offices located **(Ulica Danica 5, 48 000 Koprivnica, Croatia, Phone: +385 1 2481 214, Fax: +385 1 2481 290)** will provide complete medical care and financial compensation for injury and death as per current applicable regulatory requirements.

7. USE OF OTHER PARTIES' NAMES

The Site shall not use SPONSOR's or AXIS's name or the name of any party hereto in connection with any advertising or promotion of any product or service without the prior written permission from Sponsor/ AXIS.

8. INDEPENDENT CONTRACTORS

Site shall perform services under this Agreement only as an independent contractor, and nothing contained herein shall be construed to be inconsistent with that relationship or status. This Agreement shall not constitute, create, or in any way be interpreted as, a joint venture, partnership, or business organization of any kind.

9. INSURANCE AND INDEMNIFICATION

INSURANCE:

Institution shall maintain medical professional liability insurance with limits in accordance with local standards for each medical professional involved in the Study, or require that each medical professional maintain such insurance. Upon AXIS's request, Institution shall have its insurance carrier (or shall cause the medical professional to have his or her insurance carrier) furnish the certificate to AXIS that all insurance required under this Agreement is in force.

INDEMNIFICATION:
SPONSOR shall indemnify the Investigator and Institution (including Principal Investigator's and institution's affiliates, contractors, agents, fellows, employees and servants collectively "Indemnity") for any damages and liabilities including reasonable attorney fees as a result of any claim or lawsuit against Investigator or Institution arising directly out of the performance of the study pursuant to the protocol; provided however,

- SPONSOR will not indemnify any Indemnity for Loss to the extent and the Loss arose out of an Indemnities failure to conduct the Study in accordance with: (1) the Protocol except allowing for Protocol deviations which were medically necessary for a patient's safety or well-being and which were communicated to and accepted by AXIS/Sponsor, (2) any other instructions by Sponsor, concerning the Study drug or device or a Study procedure, or (3) applicable local, state and central laws;
- SPONSOR will not indemnify any Indemnity for Loss to the extent the Loss arising out of the negligence or wrongful acts or omissions of an Indemnities or any other person patient to an Indemnities control;
- SPONSOR must be promptly notified in writing of any claim (and no later than thirty (30) days after an Indemnitee had notice of such claim) for which indemnification is sought; and
- SPONSOR, will have sole control over the defense or settlement of any claim for which indemnification is sought, and the Indemnitees will reasonably cooperate with SPONSOR and its legal representatives in the defense or settlement of the claim; provided that SPONSOR shall act in good faith with respect to the defense or settlement and provided that the Indemnitees may, at their own expense, seek the advice of independent legal counsel.
- SPONSOR shall maintain appropriate insurance coverage in respect of its potential liability. Upon written request SPONSOR, shall provide Institution with written evidence of its insurance program.
- SPONSOR may offer Study subjects compensation for Study-related injuries, through the Study's informed consent process. If Institution provides a Study subject medical care for which compensation is available from SPONSOR, under the terms of the informed consent for the Study, SPONSOR, agrees, subject to the Study subject's authorization, to pay Institution directly on the Study subject's behalf, for the care provided.

10. MONITORING; AUDIT; REGULATORY INSPECTIONS

The Site shall permit authorized personnel of the SPONSOR/ SPONSOR designee, AXIS and any Regulatory Authority including Ethics Committee to inspect the facilities the Site proposes to use for the Study; before, during and after the Study. There will be AXIS and sponsor audits during the study apart from the monitoring visit as per the mutually agreed dates

The Site shall notify AXIS or Sponsor immediately by telephone or facsimile if the Drugs Controller General-India, or any other governmental or regulatory authority requests permission to or does inspect the Site's facilities or research records relating to this Study whenever and will provide in writing to AXIS copies of all materials, correspondence, statements, forms and records which the Site receives, obtains, or generates pursuant to any such inspection.

The Site will permit to Sponsor/Axis/EMEA/DCGI other regulatory authorities

a) Examine, inspect and audit the work performed here under and the facilities, systems and equipment at or with which the work is conducted.
b) Inspect and copy all data, documents and records related to such work and the study

The obligations of this Section shall survive termination of this Agreement.

Sponsor/Third-party Monitoring visits:

1. Third party appointed by Sponsor will do the following visits
   - During SIV one day visits along with AXIS.
   - During 50 % enrolment is over for 1 day
   - Pre closure visit for 1 day
2. **Monitoring visits: Monitoring visits will be carried out 4/5 times by Axis CRA depending on site enrollment status, excluding site closeout visit and any other emergency visits.**

Axis QA Audit Visits:

- Axis QA will do three visits – 1 SIV one day visits along with AXIS CRA.
- Site after completing of at least 1 or 2 patients enrolment for source data & eCRF verification per visit 2 days or depending on site enrollment status.

11. TERM; WAIVER; SEVERABILITY

Unless earlier terminated in accordance with the provisions of this Agreement, the term of this agreement shall commence on the Effective Date and shall terminate 18 months after the Effective Date.

This Agreement will become effective upon the date it is fully executed by all parties and shall continue in effect for the full duration of the Study according to the Protocol unless sooner terminated in accordance with the provisions of this Agreement.

This Agreement may be terminated by either party upon giving at least a thirty (30) days notice to that effect to the other party. A reasonable adjustment will be made between the parties to ensure the Site is reimbursed for project costs incurred to the date of termination of this Agreement. Any funds paid by AXIS to the Institution in excess of project costs will be returned to the AXIS.

AXIS or SPONSOR may terminate this Agreement, in whole or in part, with or without cause, immediately upon written notice to Institution. Notice by either AXIS or SPONSOR that the Study is terminated shall also constitute effective notice of termination of this Agreement.

12. EFFECT OF TERMINATION

(1) Upon notice of termination of this Agreement by either Institution or SPONSOR or AXIS, Institution shall cease enrolling patients into the Study, and shall discontinue conduct of the Study as soon as is medically practicable.

(2) Upon notice of termination of this Agreement by either Institution or SPONSOR or AXIS, Institution shall use reasonable efforts to revoke any financial obligations incurred and shall avoid incurring any additional costs in connection with the Study. Institution shall be compensated only for Study-related work actually performed or reimbursed only for expenses actually and reasonably incurred through the effective date of termination which AXIS has agreed to pay as part of the Study under this Agreement. If, upon the effective date of termination, AXIS has advanced funds which are unearned by Institution, Institution shall repay such funds within sixty (60) days of the effective date of termination. In the event Institution fails to repay such funds in a timely manner, AXIS may deduct/adjust an equivalent amount from any payment then or later due from AXIS to Institution under this or any other arrangement between the parties.

(3) Upon termination of this Agreement, all unused Materials and all SPONSOR Confidential Information (except for such records that Institution is required by law or regulation to retain) in Institution's possession shall be promptly delivered to SPONSOR at SPONSOR's expense, or, at SPONSOR's option, destroyed with the destruction must be certified in writing.

13. AMENDMENT

This agreement and protocol may only be extended, renewed or otherwise amended by the mutual written consent of the parties hereto. The parties agree that this agreement constitutes the sole, full and complete agreement by and between the parties and supersedes all other written and oral agreements and representation between the parties with respective to the study. No amendments, changes, additions, deletions, or modifications to or of this agreement shall be valid unless reduced to writing and signed by the parties.

All changes and amendments to this agreement shall be agreed in writing between the parties.

14. RECORDKEEPING/ DOCUMENT ARCHIVAL/ AND INVESTIGATIONAL PRODUCT RETENTION

Investigational Product/s will be retained either at Site or Third party archival facility after having a mutually agreed decision with Sponsor, AXIS and Sites. The Investigational product will be re-packed and sealed as per the requirements and retained at the site / Third party facility. In case if the IPs are retaining at third party facility, Site and Third party will have one agreement for the transfer of IP as per the required conditions. The payments towards the maintenance of retained samples at third party facility will be paid by AXIS on the receipt of Invoice from Third party. The Archival Charges for retaining the samples at the sites if any will be mentioned in the CTA and will be paid in due course of time. In case of retrieval requirement for the regulatory authority requirements, site will inform first to AXIS by mail requesting for the retrieval of IP, after obtaining the response from AXIS site will inform the Third party facility about the retrieval as per the procedure. Any charges related to retrieval of the IPs/ documents AXIS will reimburse the same to the Third party facility against proper Invoice. Under no other circumstances sites will not be having any authority related to retrieval of retained IP/documents at any time.

Institution or investigator shall retain all records and documents pertaining to the trial and ensure the storage of data related to study in accordance with the requirements of current Good Clinical Practices, in suitable and secured storage facilities and under appropriate conditions, for a period of time required under the applicable laws and regulations in INDIA or until at least 5 years after completion of all regular activity, whichever period is longer, unless to the extent that AXIS/ SPONSOR require the return or destruction of this data, in which case this request shall be complied with to the extent allowed by applicable laws and regulations. Before the destruction or deletion of such data, sponsor/Axis written approval shall be obtained.

Institution and Investigator will not use biological sample collected under the protocol in any manner or for any purpose other than that described in the protocol agreement.

15. ARCHIVAL FEE:

One time, non-refundable payment of Amount **INR 5000/- Per Year.**

a) Payment shall be used for archiving and storage of Study files by Site for a period of five (5) years.
b) In accordance with Sponsor's Protocol requirements, Institution shall maintain all Study records in a safe and secure location to allow easy and timely retrieval, when needed.
c) Payment shall be used for archiving and storage of Study files by Institution for a period of fifteen years,
d) Payment shall be made upon completion and receipt by CRO of all original contractual and regulatory documentation, and receipt by CRO of original invoice.

16. LIST OF STUDY INSTRUMENTS

The Investigator / Site agrees to exercise adequate care in handling of study instruments (Listed below if any) provided by AXIS/Sponsor. The Investigator / Site agrees to utilize study instruments solely in accordance with the protocol and to return to Axis/ Sponsor at the time of study Completion.

1. Camera with Tripod
2. Thermohygrometer

The last payment will be released against the receipt of the above mentioned Instruments along with the other terms and conditions mentioned in the CTA. In case any instruments have been broken due to mishandling / negligence will be repaired or will be purchased new and the same amount will be deducted from the last payments until and unless a mutual agreement between Axis and institution.

17. DISCLAIMER

The Site acknowledges that the Sponsor has engaged AXIS to manage the Study. AXIS has performed no independent research or analysis regarding the safety or efficacy of the Investigational Product, materials or treatment procedures that are to be administered pursuant to the Study and therefore AXIS makes no warranties, expressed or implied concerning the Investigational Product, materials, treatment procedures, results to be obtained in administering the Investigational Product, or the Investigational Product's fitness for any particular purpose.

18. PUBLICATION

The parties acknowledge that the Sponsor shall retain ownership of all original Data that result from this Study. Data generated during the clinical study is the sole property of the sponsor. Therefore, Principal investigator agrees not to publish or present the results or any information derived from the study.

19. GOVERNING LAW AND DISPUTE RESOLUTION

This Agreement shall be governed by and interpreted in accordance with the laws of India, without conflict of laws or principles. Any dispute between the Parties as to construction, meaning or effect of the Agreement or any clause contained therein or the rights, duties, liabilities and obligations of either Party there under, shall be resolved mutually within thirty days, failing which, shall be referred to arbitration before a sole arbitrator appointed by the Parties. The arbitration proceedings shall be conducted in accordance with the Arbitration and Conciliation Act, 1996 and rules made thereof in Hyderabad. The arbitration proceedings shall be conducted in the English language. The arbitrators' decision shall be final and legally binding and judgment may be entered thereon before the courts of competent jurisdiction. The arbitrator shall also decide on the costs of the arbitration proceedings.

IN TESTIMONY WHEREOF, the parties hereto have caused this instrument to be executed, in duplicate, by their officers, thereunto duly authorized to sign on behalf of the party.

1. **Principal Investigator**

Represented by (Name) : **Dr. Kishan Ninama**

Title : **Principal Investigator**

Signature & date and Stamp : 27/11/19

2. **Site Name** : **Sumandeep Vidyapeeth an Institution Deemed to be University**

Represented by (Name) : **Dr. Chandramani More**

Title : **Registrar**

Signature & date and Stamp : 28/11/19

Sumandeep Vidyapeeth • Deemed University •

Witness

Represented by (Name) : **Dr. Avinash K. Seth**

Title : **Research Director**

Signature & date and Stamp : 28/11/2019

3. **AXIS Clinicals Ltd**

Represented by (Name) : **Mr. Phani Bhushan Reddy**

Title : **Executive Director**

Signature & date And stamp : 16/11/19

AXIS CLINICALS LIMITED HYD.

Witness

Represented by (Name) : **Dr. Subhra Lahiri**

Title : **AVP & HOD (Clinical Research)**

Signature & date and stamp : Subhra Lahiri. 16/11/19

AXIS CLINICALS LIMITED HYD.

SUMANDEEP VIDYAPEETH

EXHIBIT A

It is agreed that the Site will receive **INR 32500/-(Rupees thirty two thousand five hundred only)** till 01 to 25 completed subject and **INR 37500/- (Rupees thirty seven thousand five hundred only) from 26th** completed subject onward as mentioned in page # 4 (**A completed, and evaluable patient defined as**)for the Study according to the schedule indicated below. This per subject amount is intended to cover the following study- related costs incurred by the Site which includes (costs related to the investigator and study team efforts towards subject visits, Study related communications, Institute service charges and Overheads & hospitalization fees etc., also included). Completed Subjects will be paid **INR 2500/- (Rupees two thousand five hundred Only)** as a reimbursement for loss of daily wages due to participation in study. In case of early withdrawal of subjects, the reimbursement can be provided on Pro-rata basis.

Investigator Fees and Hospitalization charges confirmed are inclusive of applicable tax (TDS- Tax Deduction at Source). There will be no TDS deduction for the Subject reimbursement provided the voucher will be forwarded to Sponsor before claiming of the same.

Visit No./Day	**Investigator Fees**	**Serum Pregnancy Test**	**Patient Compe nsation**	**Facial Photography**	**Total**
Visit-1 Screening/Rando mization	5850	450	500	300	7100
Visit-2 / Day 14	5300	NA	500	300	6100
Visit-3 / Day 28	5300	NA	500	300	6100
Visit-4 / Day 56	5300	NA	500	300	6100
Visit-5 / Day 84 (EOS)	6300	NA	500	300	7100
TOTAL	**28050**	**450**	**2500**	**1500**	32500
	Per each completed patient (1 to 25).				**INR 32500*/-**

From 26th patient onwards applicable.

Visit No./Day	**Investigator Fees**	**Serum Pregnancy Test**	**Patient Compen-sation**	**Facial Photo-graphy**	**Total**
Visit-1 Screening/Randomization	6500	450	500	300	7750
Visit-2 / Day 14	6000	NA	500	300	6800
Visit-3 / Day 28	6000	NA	500	300	6800
Visit-4 / Day 56	6550	NA	500	300	7350
Visit-5 / Day 84 (EOS)	8000	NA	500	300	8800
TOTAL	**33050**	**450**	**2500**	**1500**	**INR 37500*/-**
For Screen failure Subject an amount of Rs.2500/- as PI Grant					

Attested CTC

30/11/2015

Vice-Chancellor
Sumandeep Vidyapeeth
An Institution Deemed to be University
Vill. Piparia, Taluka: Waghodia.
Dist. Vadodara-391 760. (Gujarat)

SUMANDEEP VIDYAPEETH