Biosphere Clinical Research Pvt Ltd
SB-02,03,04, 2nd Floor, Highland Corporate Center, Kapurbawdi Junction, Thane (W)-400607

And

Dr. Rajendra Bohra
Mahatma Gandhi Mission's Medical College and Hospital, N-6 CIDCO,Aurangabad- 431003, Maharashtra, India.

Investigator Initiated StudyAgreement

09/Sep/2020

This AGREEMENT is entered into on the date of the last signature page between:

18. Biosphere Clinical Research Pvt Ltd having its registered office at SB-02,03,04, 2nd Floor, Highland Corporate Center, Kapurbawdi Junction, Thane (W)-400607 hereby referred to as **"Biosphere clinical Research."**

2.Dr. Rajendra Bohra, having its principal place of business at Mahatma Gandhi Mission's Medical College and Hospital, N-6 CIDCO, Aurangabad- 431003, Maharashtra, India. hereby referred to as **"Investigator."**

WhereasBiosphere Clinical Research Pvt LtdandInvestigatorhave entered into an Agreement that the Researchers shall undertake the Research Project in accordance with the Research Proposal included as Schedule 1 to this Agreement, supported byMacleods Pharmaceuticals Ltd. R & D Division III Plot No. 18, Road No 09, Marol MIDC, Andheri East, 400093, Mumbai(Company), on the terms and conditions set out in this Agreement and it is appropriate that the terms of the Agreement be set down in writing, IT IS HEREBY AGREED BY AND BETWEEN THE PARTIES HERETO as follows:

18. **DEFINITIONS**

18.1. In this Agreement:

"**Commencement Date**" shall mean **09 September, 2020**, notwithstanding the date on which the last party signed this Agreement;
"**Completion Date**" shall mean After 4 Months, being the date on which the Researchers shall deliver to the Research Centre a copy of the draft report arising from the Research Project;
"**Force Majeure Events**" has the meaning provided in clause 11;
"**Intellectual Property Rights**" means (a) copyright, patents, database rights, service marks, trademarks and rights in trademarks, designs, know-how and confidential information (whether registered or unregistered); (b) applications for registration, and the right to apply for registration, for any of these rights; and (c) all other intellectual property rights and equivalent or similar forms of protection existing anywhere in the world;
"**Maximum Grant Expenditure**" means the maximum level of funding which will be provided under the terms of this Agreement, as mentioned in Appendix 1.
"Research Centre" shall mean the Research Department at Mahatma Gandhi Mission's Medical College and Hospital, N-6 CIDCO, Aurangabad- 431003, Maharashtra, India.
"Research Committee" shall mean the Ethics Committee of Mahatma Gandhi Mission's Medical College and Hospital, N-6 CIDCO, Aurangabad- 431003, Maharashtra, India.;
"**Research Project**" means the research project.
"**Research Proposal**" means the proposal and application form included as Schedule 1 to this Agreement; "**Term**" means the term of this Agreement as more fully detailed in Clause 3.

1.2 References in this Agreement to any statute or any section of any statute include any statutory amendment, modification or re-enactment in force from time to time and references to any statute include any statutory instrument or regulation made under it.

1.3 In this Agreement:

(18) References to a person include an individual, a body corporate and an unincorporated association of persons; and

(b) Subject to Clause 8, references to a party to this Agreement include references to the successors or assignees (immediate or otherwise) of that party.

1.4 The section and paragraph headings used in this Agreement are inserted for convenience only and shall not affect the meaning or interpretation of this Agreement.

1.5 The Schedules to this Agreement shall form part of the Agreement.

2. NATURE OF RELATIONSHIPS BETWEEN THE PARTIES

2.1 For the avoidance of doubt, this Agreement constitutes a contract for the provision of services and shall not be held to constitute a contract of service between Biosphere Clinical Researchand Investigator.

2.2 Any staff engaged in performance of the Research Project shall be appointed by Investigator.

2.3 This Agreement shall not constitute any one of the parties to this Agreement as an agent or legal representative of any one or more of the other parties for any purpose whatsoever, nor create an association, agency, joint venture or partnership between the parties or to impose any liability attributable to such a relationship upon either party.

3. TERM

3.1 This Agreement shall come into force on the Commencement Date and will end on the Completion Date, unless terminated by one of the parties in terms of Clause 10.

4. PERFORMANCE OF THE RESEARCH PROJECT

4.1 Biosphere Clinical Researchand the Researchers agree to carry out and deliver the Research Project in accordance with the Research Proposal in Schedule 1, with all due skill and care and in accordance with the terms and conditions of this Agreement, in consideration for which Biosphere Clinical Research will perform its obligations under this Agreement and will pay sums to Investigator in accordance with Clause 5.

4.2 In carrying out and delivering the Research Project, the Researchers shall apply the research method as noted and approved in the Research Proposal. In the event that the Researchers wish to make any significant changes in respect of the research method, then a written request for approval shall be made to Biosphere Clinical Research.

4.3 The Researchers shall prepare regular written reports for submission to the Research Committee on the Interim Reporting Dates in accordance with the SOPs of Research committee.

4.4 Biosphere Clinical Research and the Researchers agree that all funds paid toInvestigator by Biosphere Clinical Research under this Agreement shall only be used to cover costs incurred in performance of the Research Project.

5. PAYMENT OF THE GRANT

5.1 Biosphere Clinical Research shall make payments to Investigator following the submission by Investigator of an invoice addressed to Biosphere Clinical Research, giving a detailed breakdown of all payments for direct expenses which have been incurred and for which a claim is being made.

5.2 Invoices submitted by Investigatorunder Clause 5.1 shall be as per the patient enrollment. The final invoice shall be submitted within three months of the completion of the Research Project.

5.3 Biosphere Clinical Research shall settle invoices submitted by Investigator within 30days of receipt, save in the event that the Research Centre, acting on behalf of Investigator, wishes to raise a dispute with any aspect of the invoice submitted, in which case the Research Centre shall, prior to the expiry of 30 days of receipt of the invoice, notify Biosphere Clinical Research of the details of the items in dispute.

5.4 No charge shall be made in respect of overhead expenses incurred by Investigatoror Researchers in respect of the Research Project.

6. INTELLECTUAL PROPERTY RIGHTS

6.1 If the report arising from the Research Project is accepted for publication in terms of Clause 8, then copyright in the work shall vest in Macleods Pharmaceuticals Ltd.

6.2 Any Intellectual Property Rights made available by any of the parties to this Agreement for use in connection with the Research Project, but not arising from and developed in the course of the Research Project, and which belongs to such party shall remain, as between the parties, the exclusive property of the party making such Intellectual Property Right available.

6.3 Each party hereby grants to the other parties a non-exclusive license to use such Intellectual Property Rights solely for the purpose of carrying out and completing the Research Project and for no other purpose whatsoever.

6.4 Investigatorand Researchers warrant to Biosphere Clinical Research that neither the Research Project, nor anything done by the Researchers in conduct of the Research Project, shall infringe any Intellectual Property Right held by a third party and that all relevant and necessary permissions have been obtained from third parties, including (but not limited to) permissions in respect of the Intellectual Property Rights.

7. RESEARCH OUTPUTS

7.1 Right of Publication: Investigatormay freely publish and disseminate the results of the Study, or otherwise publish or submit for publication an article, manuscript, abstract, report, poster, presentation, or other material containing or dealing with results of the Study {"Publication").

7.2 Review Period of Publications. Investigatorshall send Company a copy of any proposed Publication thirty {30) days prior to submission for Publication ("Review Period"). Company may comment upon, but may not make any editorial changes to the proposed Publication. Upon Company's timely written request prior to submission to Publication, Institution shall delete any Company Confidential Information in the proposed Publication. At Company's request, Institution shall delay Publication for an additional thirty (30) days in order to protect the potential patentability of an invention described therein.

8. ASSIGNMENT

Neither this Agreement, nor any right or obligation arising there under, may be assigned, in whole or in part, by any one or more of the parties to this Agreement, without the prior written consent of the other contracting parties, which consent shall not be unreasonably delayed or withheld.

9. LIABILITY

9.1 Subject to the provisions of this clause, Biosphere Clinical Research and the Researchers undertake to fully and effectively indemnify, keep indemnified and hold harmless Investigator and its officers, servants and agents at all times against all actions, proceedings, costs, claims, demands, liabilities and expenses whatsoever (including legal and other fees and disbursements) threatened against or sustained or incurred by Investigatoror any of its officers, servants or agents by reason of any breach of this Agreement by either the Investigator or the Researchers.

10. TERMINATION

10.1 If the Study is terminated by a written notice by the Company prior to completion but subsequent to the clinic start date, then Biosphere Clinical Researchin consultation with company will reimburse Investigator, within thirty (30) days of receipt of invoice for all costs incurred and irrevocably committed.

10.2 Notwithstanding the above, in case of material breach, either party may immediately terminate this Agreement by serving a notice of breach to the other. Breach shall be defined

as failure to comply with any material provision of this Agreement. Compensation/costs payable in such a case will be as per mutual agreement or as per the directive of the Arbitrator.

11. FORCE MAJEURE

11.1 No party shall be liable to any other party for any delay or non-performance of its obligations under this Agreement arising from any cause or causes beyond its reasonable control, including, without limitation, any of the following: act of God, governmental act, war, fire, flood, explosion, civil commotion or industrial dispute of a third party and, in the case of the Researchers, ill-health, accident or other extreme circumstances making it impossible or extremely impractical for the Researchers to fulfill their obligations under this Agreement ("Force Majeure Events").

11.2 Subject to the Researchers so delaying in terms of Clause 11.1 promptly notifying the Research Centre in writing of the Force Majeure Event, giving rise to the delay and the likely duration of the delay, the performance of the Researchers' obligations, to the extent affected by the delay, shall be suspended during the period that the Force Majeure Event persists. If the Force Majeure Event persists for more than 30 days, then Biosphere Clinical Research may terminate this Agreement forthwith, by providing written notice to the Researchers and the Investigator.

12. WITHHOLDING AND/OR REPAYMENT OF FUNDS

12.1 Biosphere Clinical Research may withhold any payment otherwise due to be made by it under this Agreement if Investigator or Researchers fail or default in their respective obligations under this Agreement, until such time as the failure of default is properly remedied.

13. WHOLE AGREEMENT

13.1 This Agreement contains the whole agreement between the parties relating to the subject matter of this Agreement and supersedes all previous agreements between the parties relating to this subject matter.

13.2 Subject to Clause 13.3, each party acknowledged that in entering into this Agreement it has not relied on any representation, warranty, collateral contract or other assurance (except for those set out in this Agreement and any documents included within the Schedules to the Agreement) made by or on behalf of any other party before the date of this Agreement. Each party waives all rightsremedies which, but for this Clause 15, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.

13.3 Nothing in Clause 13.2 limits or excludes any liability for fraud.

14. ILLEGALITY AND SEVERANCE

14.1 If any term of this Agreement is deemed to be, or becomes invalid or unenforceable, that term shall be construed or deemed amended to conform to applicable laws so as to be valid and enforceable or, if it cannot be so construed or deemed to be amended without altering in a material way the intentions of the contracting parties, that term shall be deleted automatically

from this Agreement and the remainder of this Agreement shall remain in full force and effect.

15. WAIVER

15.1 No waiver of any breach of any provision of this Agreement shall constitute a waiver of any prior, concurrent or subsequent breach of any other provisions hereof, and no waiver shall be effective unless made in writing and signed by an authorized representative of the relevant party.

16. LAW

16.1 This Agreement and all terms, provisions and conditions of the Research Project shall be governed by the Laws inIndia and shall be subject to the exclusive jurisdiction of the courts in Mumbai, India.

17. NOTICES

17.1 Any notice given or pursuant to this Agreement may be sent by hand or by post or by registered post or by recorded delivery service or transmitted by email or other means of telecommunication resulting in the receipt of a written communication in permanent form and if so sent or transmitted to the address of the party shown on the face of this Agreement, or to such other address as the party may by notice to the other have substituted therefore, shall be deemed effectively given on the day when in the ordinary course of the means of transmission it would first be received by the addressee in normal business hours.

18. AMENDMENTS

18.1 Notwithstanding any other provision of this Agreement, this Agreement may be amended only by an agreement in writing signed by all of the parties.

Signed for and on behalf of:

If to Site Principal Investigator:

15/09/2020

Dr. Rajendra Bohra
Mahatma Gandhi Mission's Medical College and Hospital
N-6 CIDCO, Aurangabad-431003, Maharashtra.

Professor& HOD of Pharmacology:

15/9/2020

Professor & H.O.D.
Department of Pharmacology
MGM's Medical College
Aurangabad.

Dr. Deepak Bhosle
Professor and HOD of
Pharmacology
Mahatma Gandhi Mission's Medical College and Hospital N-6 CIDCO, Aurangabad-431003, Maharashtra.

Deputy Dean :

15/9/2020

Dy. Dean

Dr. Pravin Suryawanshi
Mahatma Gandhi Mission's Medical College and Hospital N-6 CIDCO, Aurangabad-431003, Maharashtra.

If to Biosphere Clinical Research Pvt. Ltd:

09SEP2020

MUMBAI

Dr. Neeta Nargundkar,
Managing Director
Biosphere Clinical Research Pvt. Ltd.
Highland Corporate Centre, SB 02,03 & 04,
Second Floor, Near Kapurbawdi Junction,
Thane (W) 400 607

ANNEXURE I

STATEMENT OF WORK ORDER

Title of the study: Protocol No:CT-013-CeCl-2019;A Prospective, Single-center, Open label, Randomized, Parallel-group, ActivecontrolledClinical Study to Evaluate the Efficacy and Safety of Cefpodoxime Proxetil 200 mg +Clavulanic acid 125 mg versus Amoxicillin 500 mg + Clavulanic acid 125 mg in the Treatment of Patients with Upper Respiratory Tract Infections

Principal Investigatorand Site Payment-Per Patient cost is as follows:

Visit Number	Total Per Visit
Screening (Visit 1)	2000
Randomization (Visit 2)	1000
Treatment Period(Visit 3)	1000
End of Treatment (Visit 4)	1500
Safety Follow up (visit 5)	500
Total	**6000**

Note 1: The above total payment is inclusive of Investigator Fees, Sub-Investigator Fees), Subject Travel Reimbursement and Institutional Overheads.

Note 2: Investigations and Laboratory Cost to be paid at actual

Note 3: CRC payment will be 6000/month for a period 4 months.

Note 4: All the site payments will be released upon receipt of original invoice signed by authorized signatories.

Note 5: All the payments made to the payee are subject to Tax Deducted at Source (TDS) and Goods and Services Tax (GST) as per the applicable existing tax laws in the country and Biosphere will deduct the tax at the time of making the payments.

Narsinder