Ardent® Clinical Research Services
The legacy of clinical excellence

CLINICAL TRIAL AGREEMENT

Protocol # COVID 19/AYUSH-ICMR 2020/Adjunct Protocol

Study No. 3: Efficacy and Safety of Ayurvedic Fomulation-3 Yastimadhu (Glycyrrhiza galbra) as an adjunct to standard of care for the management of mild to moderate COVID 19.

This Clinical Trial Agreement ("Agreement") dated as of the date of last signature and effective as of 24th June 2020 ("Effective Date") between

Ardent Clinical Research Services ("CRO"), with principal offices located in the Office: 318, Level-3, Connaught Place, Bund Garden Road, Pune-411001, Maharashtra, India

and

Mahatma Gandhi Mission's Medical College and Hospital, with a place of business N-6, CIDCO,Aurangabad,Maharashtra,431 003 ("Institution")

and

Dr. Syed Umar Qudari ("Investigator"), with a place of business at Mahatma Gandhi Mission's Medical College and Hospital 6, CIDCO, Aurangabad,Maharashtra,431 003 ("Principal Investigator").

"Party" means CRO, Institution or Principal Investigator equally, and "Parties" shall mean all of them.

BACKGROUND

By separate agreement, CSIR-Indian Institute Of Integrative Medicine with a principal place of business at No. 3, Post Bag, Canal Rd, Jammu, Jammu and Kashmir 180001 ("Sponsor") has engaged with Ardent Clinical Research Services, a contract research organization, with a principal place of business in the Office: 318, Level-3, Connaught Place, Bund Garden Road, Pune-411001, Maharashtra, India acting as an independent contractor, to act on behalf of Sponsor for the purposes of transferring certain obligations in connection to this Agreement, said obligations including but not limited to negotiations and execution of the Agreement and payment administration for services performed and described hereunder.

Sponsor wishes to support a clinical trial with Sponsor Drug (hereinafter defined) Ayurvedic Formulation 3 encoded COVID 19/AYUSH-ICMR 2020/Adjunct Protocol entitled **"A Randomized, Open Label, Parallel Efficacy, Active Control, Multicenter Exploratory Drug Trial to Evaluate Efficacy and Safety of an Ayurvedic Formulation as Adjunct Treatment to Standard of Care for the management of Mild to Moderate COVID-19 Patients"** ("Protocol") to be conducted at Institution ("Trial") to involve patients participating in the Trial ("Trial Subjects").

The Parties agree as follows:

1. Investigators and Research Staff.

Principal Investigator. The Principal Investigator, being an employee/consultant of the Institution, will be responsible for the direction of the Trial in accordance with applicable Institution policies. The Trial will be conducted under the supervision of the Principal Investigator at Mahatma Gandhi Mission's Medical College and Hospital, N-6,CIDCO,Aurangabad,Maharashtra,431 003.

1.1 Sub investigators and Research Staff. Institution and Principal Investigator will ensure that only

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individuals who are appropriately trained and qualified assist in the conduct of the Trial as sub investigators or research staff (sub investigators and research staff collectively referred to as "Research Staff"). Principal Investigator may delegate duties and responsibilities to Research Staff only to the extent permitted by Applicable Law (hereinafter defined) governing the Trial conduct, as described below.

1.2 Obligations of Institution and Principal Investigator. Institution and Principal Investigator will ensure that Research Staff is informed of and agree to abide by all terms of this Agreement applicable to the activities they perform. Institution and Principal Investigator will assume all those responsibilities assigned under all applicable laws, rules, regulations, guidelines and standards including, without limitation, all relevant International Conference on Harmonization Good Clinical Practice ("ICH GCP") guidelines and standards and the World Medical Association Declaration of Helsinki "Ethical Principles for Medical Research Involving Human Subjects" (2013), all applicable laws and guidance relating to clinical trials of medicines and all applicable laws relating to human rights, supply of medicines legislation, legislation relating to human tissue and biological samples, and all applicable laws relating to the confidentiality, privacy and security of Trial Subject information ("Applicable Law").

1.3 No Substitution. Institution and Principal Investigator may not reassign the conduct of the Trial to a different Principal Investigator without prior written authorization from Sponsor. Any replacement Principal Investigator will be required to agree to the terms and conditions of this Agreement in a separate writing. In the event Sponsor does not approve a replacement Principal Investigator, Sponsor or CRO may terminate this Agreement in accordance with the Termination provisions below.

2. Protocol. Institution and Principal Investigator will conduct the Trial in accordance with the Protocol and Applicable Law.

2.1 Amendments. The Protocol may be modified only by a written amendment ("Protocol Amendment"), signed by Sponsor and the Principal Investigator. If applicable, the Parties acknowledge that Protocol Amendments are also subject to approval by the responsible Independent Ethics Committee ("IEC") and/or Regulatory Authority ("RA"). Sponsor may instruct a deviation from the Protocol on an emergency basis for the safety of the Trial Subjects. Institution and/or Principal Investigator will notify the responsible IEC and/or RA as soon as practicable but, in any event, no later than five (5) business days after the deviation is implemented. Any emergency deviation will be followed by written Protocol Amendment.

2.2 Emergency Deviations/Urgent Safety Measures. If the Principal Investigator determines that it is necessary to deviate from the Protocol on an emergency basis for the safety of the Trial Subjects, Institution and/or Principal Investigator will notify Sponsor and the responsible IEC and/or RA as soon as practicable but, in any event, no later than five (5) business days after the deviation is implemented.

3. IEC and RA. The Parties will ensure that the Trial is initiated only after both the Trial and the informed consent form ("ICF") are approved by an IEC and/or RA that complies with all Applicable Law. The Parties will further ensure that the Trial is subject to continuing oversight by the IEC and/or RA throughout its conduct.

4. Sponsor Drug. Sponsor will provide Institution with sufficient quantities of the Sponsor product that is being studied ("Sponsor Drug") to conduct the Trial at no cost to the Institution and Principal Investigator. If required by the Protocol and unless otherwise agreed, Sponsor will also provide placebo or comparator drug ("Comparator Drug") at no cost to the Institution and Principal Investigator.

4.1 Custody and Dispensing. Institution and Principal Investigator will adhere to Applicable Law requiring careful custody and dispensing of Sponsor Drug or Comparator Drug, as well as

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appropriate documentation of such activities.

4.2 Control. Institution and Principal Investigator will maintain appropriate control of supplies of Sponsor Drug or Comparator Drug and will not administer or dispense it to anyone who is not a Trial Subject, or provide access to it to anyone except Research Staff.

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

4.4 Ownership of Sponsor Drug. Sponsor Drug is and remains the property of Sponsor. Sponsor grants Institution and Principal Investigator no express or implied intellectual property rights in the Sponsor Drug or in any methods of making or using the Sponsor Drug.

4.5 Payment for Sponsor Drug or Comparator Drug. Institution and Principal Investigator will not charge a Trial Subject or third-party payer for Sponsor Drug or Comparator Drug or for any services reimbursed by Sponsor or its designee under this Agreement.

5. Financial Arrangements. Compensation for services provided under this Agreement will be made by way of payments in accordance with Attachment A (Payment Terms).
All amounts are inclusive of all direct, indirect, overhead and other costs, including laboratory and ancillary service charges, and will remain firm for the duration of the Trial, unless otherwise agreed in writing by the Parties.

6. Trial Subject Enrollment. Institution and Principal Investigator have agreed to enroll Trial Subjects in the Trial in accordance with the Protocol and in accordance with IEC and/or RA approval. Sponsor may discontinue Trial Subject enrollment if the total enrollment needed for a multi-center Trial has been achieved, if applicable.

7. Informed Consent. Principal Investigator shall ensure that the ICF approved by Sponsor, IEC and/or RA is signed on behalf of each Trial Subject before the first Trial related procedure starts for the Trial Subject.

8. Reporting Adverse Events and ICH GCP: Institution and Principal Investigator will report adverse events experienced by Trial Subjects at any time in accordance with instructions in the Protocol and Applicable Law.

9. Personal Data Protection and Privacy. The Parties recognize a common goal of securing all personal data and holding such information in confidence and protecting it from unauthorized disclosure. The Parties represent and warrant that they will comply with the provisions of Applicable Law relating to the confidentiality, privacy and security of such personal data. In addition, the Institution and Principal Investigator shall comply with the following provisions:

9.1 Authorization to Use and Disclose Health Information. Institution and Principal Investigator shall provide an appropriate privacy notice to each Trial Subject and obtain a written privacy authorization from each Trial Subject, complying with Applicable Law, which will enable Institution and Principal Investigator to provide Sponsor and other persons and entities designated by Sponsor access to completed case report forms ("CRFs"), source documents and all other information required by the Protocol. If such an authorization is separate from the ICF, Institution and Principal Investigator will only use the authorization that is approved by Sponsor, IEC and/or RA (if applicable).

9.2 Use of Trial Subject Personal Data. Institution and Principal Investigator will use the personal data obtained from the Trial Subjects in connection with the Trial for no purposes other than outlined in the Protocol and shall manage such personal data in accordance with Applicable Law.

9.3 Disclosure of Trial Subject Personal Data. Institution and Principal Investigator shall not disclose personal data to CRO or the Sponsor except as is required to satisfy the requirements of the Protocol, for the purpose of monitoring or adverse event reporting, or in relation to a claim or proceeding brought by a Trial Subject in connection with the Trial. In all such cases of disclosure, the Institution and Principal Investigator shall respect the "data minimization" principle of privacy, including but not limited to the following example: actual Trial Subject names shall not be included on any invoices for payment submitted by the designated payees.

10. Confidential Information. During the course of the Trial, Institution and Principal Investigator may receive or generate information that is confidential to Sponsor or a Sponsor affiliate.

11. Trial Data, Biological Samples, and Records.

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

a. Ownership of Trial Data. Subject to Institution's and/or Principal Investigator's right to publish any Trial Data and the non-exclusive license that permits certain uses, Sponsor is the exclusive owner of all Trial Data.

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

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

12. Insurance.

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

12.2 Sponsor will secure and maintain in full force and effect insurance coverage to fulfill its indemnification obligations expressed in this Agreement herein in accordance with Applicable Law.

13. Entire Agreement. This Agreement contains the complete understanding of the Parties and will, as of the Effective Date, supersede all other agreements between the Parties concerning the specific Trial. This Agreement may only be extended, renewed or otherwise amended in writing, by the mutual consent of the Parties. No waiver of any term, provision or condition of this Agreement, or breach thereof, whether by conduct or otherwise, in any one or more instances will be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or any prior, contemporaneous or subsequent breach thereof, of any other term, provision or condition of this Agreement whether of a same or different nature.

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14. Notices. All notices required under this Agreement will be in writing and be deemed to have been given when hand delivered, sent by overnight courier or certified mail, as follows, provided that all

urgent matters, such as safety reports, will be promptly communicated via telephone, and confirmed in writing:

With a copy to:

Ardent Clinical Research Services,
Office: 318, Level-3,
Connaught Place, Bund
Garden Road, Pune-411001,
Maharashtra, India
Landline: 020-48603277 Ext. No.3477,
Email ID: pranjal@ardent-cro.com

Institution:

Mahatma Gandhi Mission's Medical College and Hospital,
N-6, CIDCO, Aurangabad, Maharashtra,431 003
Attention: Dean
Telephone: 0240-2481437
Email: mgmmca@themgmgroup.com

Principal Investigator:

Dr. Syed Umar Qudari
Associate Professor,
Dept of Medicine,
Mahatma Gandhi Mission's
Medical College and Hospital,
N-6, CIDCO, Aurangabad,
Maharashtra,431 003

Telephone: 7558404702
Email: umarazmed@gmail.com

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ATTACHMENT A

PAYMENT TERMS

1. A sum of 15,000 per patient (PI/Co-I, CRC) (Fifteen Thousand Rupees only) shall be paid for completed patient.
2. Ethics Committee fees will be paid if required.
3. CRO will be the responsible party for all lab payment.
4. INR 750 per scheduled visit (post discharge) will be paid Payee details:

Payee Name: MGM Medical College

Payee Bank Account Details:
Bank Name: IDBI Bank
Bank Address: Bank Address: Survey No.20292, Ratnaprabha Building, kesarsingpura, Opp. LIC Building, Adalat Road, aurangabad-431001
Bank Account Number: 0376104000000107
IFSC Code: IBKL0000376

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

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[SIGNATURE PAGE FOLLOWS]

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

Agreed to and accepted:

CRO

Signature

Mr. Chandu Devanpally
Printed Name

Founder and Managing director
Title

24 | June | 20
Date

Ardent Clinical Research Service ★ Pune

INSTITUTION

Signature

Dr. Rajendra Bohra
Printed Name

Dean
Title

29 Jun 2020
Date

DEAN
MGM'S MEDICAL COLLEGE
AURANGABAD

PRINCIPAL INVESTIGATOR

Signature

Dr Syed Umar Quadari
Printed Name

Principal Investigator
Title

27 Jun 2020
Date

Dr. SYED UMAR QUADRI
M.B.B.S. M.D. (MED.)
Asst. Prof. of Medicine
MGM Medical College & Hospital A'bad.
REG. NO. 2005/02/0904

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