

తెలంగాణ తెలంగాణ TELANGANA

K. Geetha Rani  
AA 580781

Sl. No. 19581, Date: 17/11/2020  
Sold To: ABHISHEK CHAKRABORTY  
S/o. B. CHAKRABORTY, R/o. HYDERABAD  
For Whom: BHARAT BIOTECH INTERNATIONAL LIMITED

**KODALI GEETHA RANI**  
LICENSED STAMP VENDOR  
L No:16-04-001/2013  
R L No:16-04-004/2019  
# 8-3-191/132, 167/C, BEHIND E-SEVA  
VENGAL RAO NAGAR, HYDERABAD-500038  
Cell: 94920 25252

## Memorandum of Understanding

This Memorandum of Understanding [Hereinafter referred to as “MOU”] is entered into as of 24<sup>th</sup> day of November, 2020 (the “Effective Date”), by and between:

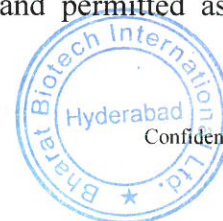
**Bharat Biotech International Limited**, a company incorporated as per the Companies Act, 1956, having its registered office situated at Genome Valley, Shameerpet, Hyderabad – 500 078, Telangana, India, (which term shall include its successors, and permitted assigns) [Hereinafter referred to as “BBIL”], of the FIRST PART;

AND

**Precisa Comercialização de Medicamentos Ltda**, a company incorporated under the laws of Brazil, having its registered office Av. Portugal, 1100 - Rua 5 Parte A 14 A-Itapevi, SP Cep: 06696-060, (hereinafter referred to as “PRECISA”), which term shall include its successors, affiliates, subsidiaries and permitted assigns of the SECOND PART;

AND

**Envixia Pharmaceuticals LLC**, a company in International Free Zone Authority, Fujairah - UAE having its registered office at Kidnah, Block A, Plot 4, Fujairah - UAE, (hereinafter referred to as “Envixia”), which term shall include its successors, affiliates, subsidiaries and permitted assigns of the THIRD PART;





hereinafter are also referred to, individually, as a “Party”, or, jointly, or cumulatively, as the “Parties”.

**WHEREAS**, BBIL is a leading manufacturer of vaccines and bio-pharmaceuticals in India, and has considerable technology, trade secret, know-how and research experience in relation to the manufacturing and commercial production of vaccines and bio-therapeutics and has also established its marketing and distribution network for such product(s) in India as well as abroad;

**AND WHEREAS**, PRECISA is a company with more than 20 years of experience in the Brazilian health market, specializing in importing and distributing large volumes of health products as well as acting in an innovative way together with other major Brazilian and international companies.

**AND WHEREAS**, Envixia is well versed in Import and Trade of Medicines, Medical Devices and Equipment,

**AND WHEREAS**, the Parties wish to initiate discussion regarding business relationship for introduction of BBILs COVID-19 vaccine candidate COVAXIN™, in Brazil [Hereinafter referred to as the “Purpose”].

**AND WHEREAS**, each Party acknowledges that for the effective performance under this Agreement and for the smooth functioning of the Purpose, each Party requires to oblige with the commitments made under this MOU to the best of its capacity in utmost good faith.

**AND WHEREAS**, the Parties wish to assure the protection and preservation of certain confidential and/or proprietary information to be disclosed or made available by or on behalf of one party to the other party in the course of their discussions (including strategic, commercial, clinical or scientific), if any, or in discussions concerning an eventual collaboration (including, without limitation, technical, strategic, commercial, clinical or scientific) between them.

**AND NOW, THEREFORE**, in view of the mutual premises and covenants contained herein and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, **AND INTENDING TO BE LEGALLY BOUND** the Parties agree as follows:

## **1. TERMS OF THE MOU**

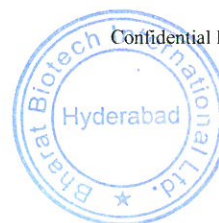
- 1.1. Collaboration-** Presica, Envixia and BBIL hereby agree to this MOU, under which the Parties intend to collaborate with respect to the Purpose. The Parties’ mutual obligations under such collaboration shall be as set forth herein as Schedule 1 to this Agreement.

## **2. TERM AND TERMINATION**

- 2.1. Term** - This MOU shall become effective as of the Effective Date and shall be effective for Two (02) years from the Effective Date, unless both Parties agree to extend the MOU in writing or unless terminated earlier by either Party under Section 2.2 of this Agreement.
- 2.2. Termination of this MOU** - Either Party may terminate this MOU for any reason or for no reason upon Thirty (30) days’ written notice to the other Party.

## **3. CONFIDENTIALITY AND PUBLICITY**

- 3.1. Nondisclosure and Non-use Obligations** - At all times during the term of this MOU and for a



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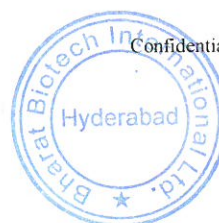
period of three (03) years following termination or expiration hereof, each Party shall, and shall cause its officers, directors, employees and agents, to not disclose and not use any Confidential Information provided or otherwise made known to it by the other Party, except to the extent such disclosure or use is expressly permitted by the terms of this MOU or is reasonably necessary for the performance of this MOU. The Confidentiality obligations shall survive with respect to trade secrets so long as the Disclosing Party owning the trade secrets places the other Parties on written prior notice that such Confidential Information shall be treated as "trade secret", and such Confidential Information retains its trade secret status. No Party shall make any non-permitted use of the Confidential Information without the disclosing party's specific prior written authorization.

**3.2. Confidential Information** - All information, whether in oral, written, graphic, electronic or other form (including copies thereof), including, but not limited to, information, data, trade secrets, formulas, processes, product ideas, know-how, a sample or model, that is disclosed by or on behalf of a Party (the "**Disclosing Party**") to the other Party (the "**Receiving Party**") under this Agreement, shall be deemed to be "**Confidential Information**". For purposes of this MOU, "**Confidential Information**" means any and all any and all information or material of a Party, including but not limited to the terms of this MOU or information or material relating to the trade-secret, know-how, product dossier, patent (whether application or granted), trademarks, intellectual property (whether or not protectable), clinical trial data/information, reports, scientific, regulatory or business information or other activity of either Party that is disclosed to the other Party in connection with this MOU in writing or in any form or media (or orally or visually) whether or not marked confidential. Notwithstanding the foregoing, Confidential Information shall not include any information that:

- 3.2.1. is or becomes part of the public domain through no wrongful act, fault or negligence on the part of the receiving Party;
- 3.2.2. is available from other sources who are not under any obligation of confidentiality with respect to the information;
- 3.2.3. has been made available by the providing Party to others without any obligation of confidentiality;
- 3.2.4. is already in the possession of the receiving Party at the time of disclosure, as evidenced by documentation or other competent evidence; or
- 3.2.5. has been independently developed by or for the receiving Party without reference to the providing Party's Confidential Information, as evidenced by documentation or other competent evidence.

Notwithstanding any other provisions of this Agreement it shall not be a breach of this Agreement for any Party to disclose any Confidential Information pursuant to a court order or a binding request from a statutory or regulatory (or other analogous) authority with jurisdiction to require the disclosure of such Information, provided that the Receiving Party gives all reasonable notice(s) in writing in advance, of such disclosure to the other Party, provide reasonable opportunity to review the disclosure before it is made and to interpose its own objection to the disclosure and limits the disclosure to the extent necessary to comply with such request.

**3.3. Publications** - Each Party shall have the right to present, publish and otherwise publicly disclose information it has developed or discovered in joint activities *provided* that (a) it does not disclose any Confidential Information of the other Party in such disclosure (except as expressly permitted hereunder); and (b) it provides the other Party with advance copies of each such proposed disclosure at least thirty (30) days before the submission for presentation, publication or other disclosure. Upon request by the non-publishing Party within such thirty (30) day period, the



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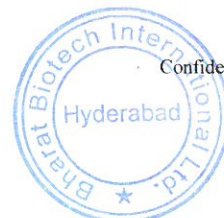


publication will be withheld for an additional thirty (30) days. Each Party will receive credit, if requested, in writing for its support in the discovery or development of the information. The rights over the authorship shall be determined by the acceptable modes as practiced for publication rights.

- 3.4. Use of Party's Name** - Neither Party may use the name of the other Party in any advertising or publicity material nor in any other publication or make representation or statement without first having obtained the other Party's written permission. Neither Party shall issue any press release or other public statement concerning this MOU or other joint activities without the prior written consent of the other Party.
- 3.5. Return of Confidential Information** - All copies, including but not limited to notes, product dossier, reports, clinical trial data and other written, printed or other tangible materials, whether documented or stored in written, graphic, electronic, magnetic or any other form, of Confidential Information shall be destroyed or returned to the Disclosing Party upon request or upon expiration or at early termination of this Agreement at any time, and in any event, no later than Thirty (30) days following any expiration or termination of this Agreement, except that the Receiving Party may retain one copy of the Confidential Information for legal archival purposes. All Confidential Information of a Disclosing Party (including all copies thereof) shall be and at all times remain the property of such Disclosing Party.
- 3.6. Ownership** - Confidential Information (including all copies thereof) disclosed by the Disclosing Party hereunder shall remain the property of such Disclosing Party. Nothing in this Agreement shall be construed, by implication or otherwise, as a grant, assignment, lease, mortgage of any right or license to the Confidential Information, trademarks, inventions, copyrights or patents, as a grant of a license to either Receiving Party to use any of the Disclosing Party's Confidential Information except as expressly set forth herein, or as an obligation to enter into any further agreements relating to any Confidential Information or any possible business relationship.
- 3.7. Irreparable Harm** - The Parties acknowledge and expressly agree that any disclosure, in violation of this Agreement, of the Information by the Receiving Party thereof could be detrimental to the Disclosing Party's business and may cause it irreparable harm and damage. In accordance with applicable law and in addition to any other rights and remedies provided herein, such Disclosing Party shall be entitled to seek equitable relief by way of injunction or otherwise.

#### **4. LIABILITY AND INDEMNIFICATION**

- 4.1. Mutual Representations** - Each Party hereby represents and warrants to the other Party that (a) it has the requisite power and authority to enter into this MOU and to perform according to its terms, and that the official signing this MOU has the authority to do so; (b) the execution, delivery and performance by the Party of this MOU do not and will not contravene or conflict with the governing documents of the Party or any applicable laws, or constitute a default in any material respect under any agreement or instrument to which the Party is a party; and (c) it is financially able to satisfy all funding commitments made in any joint activities.
- 4.2. DISCLAIMER OF REPRESENTATIONS AND WARRANTIES** - EXCEPT FOR THE REPRESENTATIONS AND WARRANTIES PROVIDED IN SECTION 4.1 OF THIS MOU, NEITHER PARTY MAKES ANY REPRESENTATION OR GRANTS ANY WARRANTY HEREUNDER, TO THE OTHER PARTY, WHETHER EXPRESS OR IMPLIED, AS TO ANY MATTER WHATSOEVER.
- 4.3. Indemnification** - Each Party shall defend, indemnify and hold harmless the other Party, its



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Affiliates and their respective directors, officers, employees and agents from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) in connection with any and all suits, investigations, claims or demands of third parties arising from or occurring as a result of: (a) any material breach by the indemnifying Party of this MOU, (b) the gross negligence or willful misconduct on the part of the indemnifying Party or its Affiliates or their respective directors, officers, employees, and agents in the performance of obligations or exercise of rights under this MOU, or (c) any violation of applicable law by the indemnifying Party or its Affiliates or their respective directors, officers, employees, and agents in the performance of obligations or exercise of rights under this MOU, except, in each case ((a)-(c)), for those Losses for which the indemnified Party has an obligation to indemnify the indemnifying Party pursuant to this Section 4.3, as to which Losses each Party shall indemnify the other only to the extent of their respective liability.

**4.4. LIMITATION ON LIABILITY - IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, OR FOR LOST REVENUE, WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE, ARISING OUT OF ANY BREACH OF OR FAILURE TO PERFORM ANY OF THE PROVISIONS OF THIS MOU.**

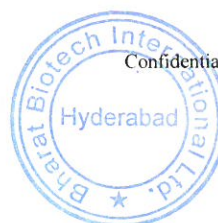
**5. GOVERNING LAW AND DISPUTE RESOLUTION**

- 5.1. Governing Law** - This MOU shall be governed by and construed in accordance with the laws of India.
- 5.2. Arbitration** - Any dispute or controversy arising out of this MOU that cannot be settled amicably by the Parties shall be resolved by binding arbitration under Arbitration and Conciliation Act, 1996. The place of arbitration shall be Hyderabad, India. Nothing in this Section 5.2 shall preclude either Party from seeking interim or provisional relief, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a dispute either prior to or during any arbitration if necessary, to protect the interests of such Party.

**6. INTELLECTUAL PROPERTY RIGHTS**

**6.1 Definitions:**

- (a) **"Invention"** shall mean any discovery, concept, or idea, whether or not patentable, and arising directly from the performance of the Purpose under this MOU, including but not limited to processes, methods, software, tangible research products, formulas and techniques, improvements thereto, and know-how related thereto.
- (b) **"Intellectual Property Rights"** shall mean patents, trademarks, trade names, service marks, domain names copyrights, trade-secret, Know-How, natural, hybrid, recombinant and synthetic biological material and improvements and modifications therein, rights in and to databases (including rights to prevent the extraction or reutilization of information from a database), design rights, topography rights and all rights or forms of protection of a similar nature or having equivalent or the similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered/granted and/or either may include applications for registration of any of them or may not have applied for registration but still would be considered to include as Intellectual Property.



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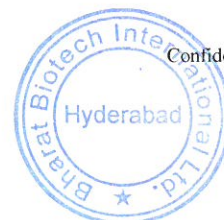
- (c) **“Know How”** shall mean all technical and other information which is not in the public domain (other than as a result of a breach of confidence), including but not limited to information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, procedures, designs for experiments and tests and results of experimentation and testing, processes, specifications and techniques, laboratory records, clinical data, manufacturing data and information contained in submissions to regulatory authorities, whether or not protected by Intellectual Property Rights or any applications for such rights.

**6.2** Each Party shall remain sole owner and has exclusive rights, title and interests, on any and all of the Intellectual Property Rights, which has been conceived or developed, at any time, independent of the other Party under this MOU.

**6.3** All rights, title and interests in any Invention, Intellectual Property Rights conceived, developed and/or reduced to practice as a direct or indirect result of the performance by either of the Parties under this Agreement shall solely belong to BBIL. BBIL shall be solely responsible for expenses incurred in the filing, prosecution, issuance and/ or maintenance of any patent application or patent issuing thereon. Further prosecution, litigation and costs including attorney's fee, if any, shall thereafter be borne by BBIL. Presica and Envixia shall cooperate with BBIL, in good faith and in the best of its capability, to support with documents and information, as may be necessary for successful implementation, including without limitation, documentation, prosecution and litigation proceedings.

## **7. MISCELLANEOUS**

- 7.1. Waiver** - No failure or delay on the part of either party in exercising any right, power or privilege under this MOU will operate as waiver thereof, nor will any single or partial exercise of any such right, power or privilege operate as a waiver of any subsequent exercise thereof.
- 7.2. Assignment** - Without the prior written consent of the other Party, neither Party shall sell, transfer, assign, delegate, pledge or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this MOU, or any of its rights or duties hereunder or thereunder.
- 7.3. Notices** - All notices under this MOU shall be in writing and shall be deemed to be given when personally delivered or when sent by fax or when sent by confirmed e-mail or when sent by post to the address of the party set out in this MOU.
- 7.4. Independent Contractors** - The relationship of the Parties is that of independent contractors and not agents of each other or jointventures or partners, regardless of whether either or both Parties establish an office in the headquarters of the other Party. Each Party shall maintain sole and exclusive control over its personnel and operations. Neither Party shall have the power to bind or obligate the other Party in any manner, including in connection with fundraising, grant-writing, advocacy and policy-related activities.
- 7.5. Entire MOU** - This MOU constitutes the entire agreement between the Parties pertaining to the subject matter hereof and supersedes all prior oral or written agreements, understanding, negotiations and discussions between the Parties pertaining to such subject matter.
- 7.6. Amendments** - If either Party desires a modification to or extension of this MOU, the Parties shall, upon reasonable notice of the proposed modification or extension, confer in good faith to determine the desirability of such modification or extension. Such modification or extension shall not be effective until a written amendment is executed by the duly authorized representatives of



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each Party.

- 7.7. **Severability** - In the event that any provision of this MOU is deemed illegal, invalid or unenforceable under present or future laws, it shall be ineffective to the extent of such invalidity, illegality or unenforceability without affecting in any way the remaining provisions or conditions of this MOU. The Parties shall remain legally bound by the remaining terms of this MOU and shall strive to reform the MOU in a manner consistent with the original intent of the Parties.
- 7.8. **Force-majeure** - If at any time during the existence of this MOU, either party is unable to perform whole or in part any of its obligations because of war, hostility, military operations of any character, acts of Government, sabotage, fire, floods, explosions, epidemics, strikes and any other matter which are beyond human control, then the date of any obligation under this MOU shall be postponed during the time for which such circumstances are operative.
- 7.9. **Counterparts; Facsimile Execution** - This MOU may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This MOU may be executed by facsimile or electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their respective duly authorized representatives on the place, day and year appearing above their respective names:-

<p>Signed and delivered on behalf of: <b>Bharat Biotech International Limited</b></p> <p>By:  Name: <u>Dr. V. Krishna Mohan</u> Title: <u>Whole-time Director</u> Date: <u>29/01/2020</u></p> <p>Witness (In the presence of) 1. <u>Apoorv Kumar</u></p> <p>( Company stamp )</p>	<p>Signed and delivered on behalf of: <b>Precisa Medicamentos Limitada</b></p> <p>By:  Name: <u>Mr. Francisco Maximiano</u> Title: <u>President</u> Date: <u>24-11-20</u></p> <p>Witness (In the presence of) 1. _____</p> <p>( Company stamp )</p>	<p>Signed and delivered on behalf of: <b>Envixia Pharmaceuticals LLC</b></p> <p>By:  Name: <u>Mr. Anudesh Goyal</u> Title: <u>General Manager</u> Date: <u>02/02/2021</u></p> <p>Witness (In the presence of) 1. <u>KEMISHA SANGHVI</u></p> <p>( Company stamp )</p>
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## Schedule 1

### Scope of Work

#### 1. Overview

BBIL's Covid-19 Vaccine shall undergo local clinical trials in Brazil and shall apply for registration and approval by the Brazilian regulatory authorities for distribution in Brazil.

#### 2. Roles and responsibilities of BBIL:

- A. Research and development (R&D) and manufacture of the Covid-19 vaccine with the highest standards;
- B. Provide guidance on clinical trial design and protocols;
- C. Shall only provide technical support from India to the appointed Clinical Research Organization (CRO). The CRO and the regional entities shall be responsible for staging and monitoring of clinical trial;
- D. Provide Presica all necessary documents to support all forms of regulatory filings;
- E. BBIL shall allocate vaccine stocks for Brazil (via Presica), once Presica provides an Advanced Market Commitment (AMC) and after mutual discussion number of doses to be allocated, and the price is decided, which Presica will have to confirm by a certain date;
- F. Support Presica's marketing activities relating to presentation of data on BBIL's vaccine. BBIL shall only provide clinical data as and when available publically in order to present to various medical boards and key opinion leaders.
- G. Shall appoint Presica as an exclusive distributor for BBILs COVID-19 vaccine candidate in Brazil provided the following conditions have been met:
  - i. The Indian Government provides consent to export BBILs COVID-19 vaccine candidate.
  - ii. All regulatory clearances in India and Brazil have been achieved.

#### 3. Roles and responsibilities of Presica:

- A. Apply for local clinical trial and secure approval of the Covid-19 Vaccine from regulator(s) in Brazil, if needed;
- B. Sponsor / co-finance local clinical trial of the Covid-19 Vaccine, if needed;
- C. Appoint and fund CRO, principal investigator(s) and other related expenses;
- D. File for certificate of product registration (CPR) or certificate of exemption (COE) or applicable permit to import and distribute the Covid-19 Vaccine;
- E. Import and distribute the Covid-19 Vaccine for both private sector and public sector (government).

#### 4. Roles and responsibilities of Envixia:

- A. Provide support for all activities related to registering and commercializing BBILs COVID-19 vaccine in Brazil.

