EX-99.1 2 ex99_1.htm EXHIBIT 99.1

Contract No.: YF202011-A Contract Date: 13th-Nov-2020

The Ii-key innovative vaccine development agreement

Parties:

Party A: Project initiator

Beijing Youfeng International Consulting Co., Ltd

1-806 Huirunyuan Jingtong Expy, Shilipu, Chaoyang, Beijing, China

And

Party B: Project technology investor

Generex Biotechnology Corporation

NuGenerex Immuno-Oncology Inc. (a subsidiary of Generex)

10102 USA Today Way SUITE 200, Miramar, FL 33025 Collectively called "Generex" hereafter

And

Party C: Technical Supporter

National Institute for Viral Disease Control and Prevention, Chinese Center for Disease Control and Prevention

No. 155, Changbai Road, Changping District, Beijing

And

Party D: fund provider

Beijing Guoxin Haixiang Equity Investment Partnership (Limited Partnership)

9-96, Building 6, Ronghui Park, Linkong Economic Core Area, Shunyi District, Beijing

The Joint Entity: Party A, Party B, Party C and Party D will setup a Joint research team and entity in China

Technical terms interpretation (FDA, NMPA)

FDA: U.S. Food and Drug Administration

NMPA: National Medical Products Administration (China FDA changed name to NMPA on Jan 21, 2019)

Explanation of Ii-key technology: technical mechanism, technical logic, application scenarios, intellectual property list, published literature lists, showcases of the technology and list of out licensed deals.

Following the strategic cooperation agreement, we reached this cooperation agreement, the purpose is to cooperate in the development of Generex's internationally patented Ii-Key innovative technology COVID-19 vaccine and other vaccines, so that all parties involved in this project can quickly and effectively Carry out relevant work.

WHEREAS, Party A, initiates and organizes all parties work together to establish a joint entity in China, provides other funds and financial guarantee in addition to Party D's contribution, and manages the cooperative research team to quickly develop and transfer Party B's Ii-Key Vaccine technology in China.

Whereas, Party B, owns patents and technologies related to Ii-Key peptide vaccine, and is responsible for providing technology, clinical data, patents and other exclusive rights to the Joint Entity.

Whereas, Party C, provides technical means and technical support for vaccine clinical sample testing and clinical trials (including pre-clinical research, phase I, phase II and phase III clinical trials), is responsible for technical identification, research and development, and provides technology for subsequent vaccine immunological effect evaluation support. The patent developed through the application of Party B's Technology transformation

shall be jointly owned by Party C and the Joint Entity, each owning 50% of the intellectual property right. Party C is not responsible for capital investment and does not assume any debts to the establishment of the Joint Entity.

Whereas, Party D, provides the agreed funds needed for the research and development cooperation of this project, and assists Party A in securing funding for the research and development of the project.

NOW, THEREFORE, in consideration of the above premises and of the mutual agreements and covenants herein contained, Parties have reached the following agreement:

CHAPTER 1 SCOPE OF THE TECHNOLOGY COLLABORATION

1.1 Data Sharing and Training

Party B shall disclose and permit the Joint Entity to use the following technology, including:

(1) Ii-Key-SARS-CoV-2 technology, (Technical mechanism, technical logic, application scenarios, list of intellectual property rights, list of published documents, implementation cases, list of authorized technologies) See Exhibit B; (2) technical know-how; (3) pre clinical and clinic data; and (4) background material on the Ii-Key platform pertaining to its Ii-Key Peptide Vaccine technology for the COVID-19 vaccine applications (hereafter "Party B's Technology"). At the same time, Party B shall also clarify any other related proprietary technologies and train the technical personnel of the joint entity, Party B will ensure that the future cooperative research team can independently design, screen, analyze, verify and improve the specific T cell polypeptide antigen sequence through training, cooperative research, and commissioned development, and is responsible for the safety,effectiveness and quality of the T cell polypeptide specific sequence, such work will be initiated right after the signing of the agreement to ensure the implementation of the cooperation. Once the production technology of the Ii-Key peptide vaccine is transferred, preclinical research and clinical research (phase I, phase II and phase III) will begin. To evaluate the effectiveness of the vaccine in clinical studies conducted in China.

1.2 Collaboration and Authorization

Under the technical guidance of Party C, Party A shall provide necessary facilities to the Joint Entity or Party C (if applicable). These facilities will include laboratories for Ii-Key peptide vaccine synthesis, analysis, in vivo testing, and phase I, phase II and phase III clinical research

Party B hereby authorizes the Joint Entity to use Party B's Technology as listed in Exhibit B for the research, development and commercialization of products and technology in China according to this Agreement, see Exhibit A for details of the authorization. The Joint Entity will conduct product development and research under this Agreement, and Party C will evaluate the protective efficacy of vaccines in preclinical and clinical studies of coronavirus and influenza.

Provided that all the parties have fulfilled the terms and conditions of this Agreement, Party B agrees that such authorization shall be immediately and unconditionally effective for the Joint Entity from the date of its establishment.

1.3 After the execution (signatures) of this Agreement, the Joint Entity shall pay Party B a license fee of US$5 million, Party B will provide the cooperative research team with copies of technical documents, patents, regulatory documents, and preclinical and clinical reports related to the Ii-Key-SARS-CoV-2 peptide vaccine (hereafter "Technical Information").

1.4 Party B shall provide technical training and support services related to this collaboration. The contents of the technical training and support service will be agreed upon in detail by the parties and annexed as exhibit to this Agreement.

CHAPTER 2 COLLABORATIVE TERMS AND CONDITIONS

2.1 License Fee -

Upon the entry into force of this Agreement, the Joint Entity will pay an license fee of US$5 million to Party B.

2.2 Royalty Payments

The Parties hereby agree that, Party B shall, at such time when the COVID-19 vaccine comes on to the market for the first commercial sale, receive from the Joint Entity the royalty fee, which will be paid in the following manner:

(i) by offering Party B 20% of the equity interests of the Joint Entity (as set forth in Section 2.4 below); or

(ii) by cash payment to Party B in a price equal to US$2 per dose for the COVID-19 vaccine.

2.3 Exclusivity

(1) Party B agrees that its authorization to the Joint Entity becomes a perpetual sole and exclusive license for the Joint Entity to use the technology within the licensed territory and the licensed area, and except for the Joint Entity, Party B does not and will not grant authorization or license to any third party to use such technology within the licensed territory or the licensed area. With respect to the sale of such technology in other countries outside the licensed territory, Party B agrees to then negotiate separately with the Joint Entity, and the export of such technology involving social public welfare shall not be subject to the restrictions of the licensed territory under this section.

(2) The Parties hereby agree that, The intellectual property rights of Party B's technology that be authorized to the Joint Entity to use belong to Party B; any products developed by the Joint Entity and the intellectual rights thereof (including but not limited to the patents, trademarks, copyrights, know-how, technical plan, data, filing materials, trade secrets) shall solely and exclusively be owned by the Joint Entity.

2.4 The Joint Entity equity Shares (each party will have a supplementary agreement or exclusive cooperation agreement to this agreement)

Party A: 75%

Party B: 20%

Party C: Due to the nature of Party C, it is not able to hold shares and cooperate with other Parties in the incorporation of the company, therefore, the Joint Entity will pay to Party C : RMB 1 million of the science and technology development research expenses for the preliminary science and technology development research work of the project; RMB 2 million within one month after vaccine is approved for phase I and phase II clinical trials; RMB 3 million after vaccine is approved for phase III clinical trials; and RMB 5 million after vaccine is approved for market launch. The Joint Entity will then enter into separate technical service contracts with Party C in regards to the technical services and investment of the pre-clinical research, phase I, phase II and phase III clinical trials.

Party D: 5%

The Parties hereby agree that, the capital contribution of each party in the Joint Entity and relevant shareholder rights shall be further specified in the documents of the Joint Entity (including without limitation, the shareholders agreement and the articles of association), which shall b entered into by and among the Parties. The net profits of the Joint Entity shall first be paid to Party B until it receives US$20 million license fee, the remaining net profits of the Joint Entity shall be distributed among the shareholders in accordance with the relevant documents of the Joint Entity executed by the parties.

For the avoidance of doubt , the parties agree that Party B shall not be entitled to further distribution of the net profits of the Joint Entity upon the payment of the aforesaid US$20 million license fee until the completion of distribution of the remaining US$80 million net profits of the Joint Entity to shareholders other than Party B ("Other Shareholder Distribution"); and after the completion of Other Shareholder Distribution, the other remaining net profits of the Joint Entity will be distributed among all the shareholders in proportion to their respective shareholding percentage in the Joint Entity.

CHAPTER 3 FEES AND RESPONSIBILITIES

3.1 To facilitate the implementation of the collaborative work signed in this agreement, after the cooperation framework agreement (all attachments) becomes effective, the cooperative research team intends to accept a working group sent by Party B to conduct technical training and exchange information with project participants, and discuss the Ii-key peptide vaccine the effectiveness of communication. With the Joint Entity's prior approval or confirmation, it shall bear all related expenses, including international and domestic travel expenses.

3.2 Limited responsibilities: All parties should cooperate closely to avoid any problems or disputes that may arise during the cooperation process. If cooperation is not possible due to certain technical or policy reasons, negotiations will be conducted in a friendly manner.

CHAPTER 4 GUARANTEES

4.1. Party B guarantees that:

(1) The patents, technology, trade secrets and other intellectual property rights authorized and licensed by it to the Joint Entity under this Agreement are lawfully owned and fully entitled by it, and that the ownership of such intellectual property rights and related interests are free and clear of any kind of lien or security interest; it has not been notified in writing of any claim by any third party that the development of any licensed product within the licensed territory infringes the intellectual property rights of such third party, nor has it been aware of any third party's intent to raise such claims;

(2) After its execution, delivery and performance of this Agreement requires no license, authorization or consent from any governmental agency or any other person or corporation, and such execution, delivery and performance will not result in any breach of or give rise to any right to terminate, revoke, renegotiate or accelerate, or trigger any other right under any agreement or contract relating to the licensed IP and/or licensed products;

(3) The use of the licensed technology by the Joint Entity for its business or services will not infringe the patent, trademark, copyright, trade secrets or any other rights of any organization or individual; and

(4) It will comply with the laws of both the United States and China, and will not violate any laws or regulations in connection with this cooperation.

4.2. Party B guarantees the use of vaccine adjuvants. (1) Provide relevant certification, rationality and necessity of the adjuvant application in human vaccines; (2) Dosage design mechanism and parameters (what chemical substance); (3) Provide adjuvant source (China has all raw materials and other conditions for vaccine production) (4) Provide stability instructions (5) Provide past use history of adjuvant use

4.3. Party B guarantees that the current and future Ii-key vaccine data in the U.S. or other countries in clinical trials (including clinical phase I, phase II, and phase III) and the projects (whether directly or indirectly) reported to the FDA (Regardless of race and ethnicity) to share with the Joint Entity to help the project advance quickly

4.4. Party B guarantees that the patents covered in this agreement shall be lawful and valid.

4.5. All four partners promised to ensure that all relevant Ii-Key vaccine human clinical trials will be conducted in countries with vaccine clinical trials conditions in accordance with the guidelines of the International Coordinating Committee (ICH).

4.6. The Joint Entity guarantees that it will take all necessary steps to obtain regulatory approval of the Ii-Key vaccine in the Peoples Republic of China and its territories.

4.7. Party B agrees that if the vaccine developed by itself, other authorized party or the Joint Entity fails the clinical trial, Party B will compensate the Joint Entity through one of the following methods:

a) Party B will grant the Joint Entity sole and exclusive use of its technology and related intellectual property in "Excellagen" for a license fee less than US$ IO million, and deduct 5 million from the 10 million license fee from Excellagen, an FDA-approved medical device which has 1 7 indications in wound care. The remaining 5 million will be paid following NMPA approval. For the avoidance of doubt, Excellagen is not Ii-Key product.

Excellagen trademark number 77848064

FDA 510(k) Number K110318

The introduction of "Excellagen" and its technical mechanism, technical logic, application scenarios, listing number, list of intellectual property rights, list of published documents, implementation cases, list of authorized technologies shall be annexed as Exhibit D to this Agreement.

b) Party B will cooperate with the Joint Entity in the entire Ii-Key platform pursuant to Section 10.5 of this Agreement, and Party B will grant the Joint Entity a sole and exclusive license to use its technology in the following areas with a technology license fee less than US$50 million, and deduct 5 million from 50 million license fee for whole Ii-Key platform, which includes the platforms for Infectious Diseases and Cancer.

Infectious Diseases: avian flu, influenza, and any other pandemic disease in the future.

Cancer: breast cancer, triple negative, 1+ and 2+, Bladder, Kidney, lung, liver, gastrointestinal, colon, and any other Her2 Nu expressing cancer pathways.

In addition: Melanoma with our Ii-Key GPl00

The Parties hereby agree that, further arrangements hereunder shall be agreed among the Partied by entering into further agreements.

CHAPTER 5 EFFECTIVENESS AND TERMINATION

5.1. This Agreement is signed by the representatives of all parties, and shall become effective on the date of execution or signature of this Agreement.

5.2. Termination for Breach.

Either party shall have the right to terminate this Agreement at any time: (i) within thirty (30) business days after the execution of this Agreement, the establishment of the Joint Entity has not been completed; (ii) any party fails to perform its obligations under this Agreement and fails to cure such default within ten business days after notified by written notice from any non-breaching party; (iii) within seven (7) business days after the payment of the license fee of US$ 5 million by the Joint Entity in accordance with Section 2.1 of this Agreement, if Party B has not provide relevant Technical Information to the cooperative research team, the Joint Entity may notify Party B in writing and terminate this Agreement, Party B shall return the license fee of US$ 5 million within three (3) business days since the receipt of the written notice. (iiii)Due to changes in national laws and regulations or related management provisions, the party C can not complete the framework agreement, and the party C has the right to terminate the framework agreement without any responsibility.

5.3. Continuing Obligations. Except for the termination of this Agreement pursuant to Sectiont 5.2, termination of this Agreement for any other reason shall not be construed to release any party from any obligation that matured prior to the effective date of such termination. No termination hereunder shall constitute a waiver of any rights or causes of action that either party may have for any acts or omissions or breach hereunder by the other party prior to the termination date.

5.4. Legal Effect

This agreement is legally binding between all parties.

CHAPTER 6 CONFIDENTIALITY

6.1. All parties agree: Any financial, legal, commercial or technical information (including but not limited to trade secrets) disclosed to them by Party A, Party C, Party D and Party B in response to this agreement, unless such information has been legally disclosed, otherwise. Oral disclosure through oral, written or other means shall be regarded as their respective confidential and proprietary information ("confidential information"), and shall be regarded as confidential information in accordance with the provisions of this Agreement.

6.2. Parties shall hold the Confidential Information in strictest confidence, shall use such Confidential Information solely in connection with its obligations hereunder, and shall not take any action in derogation of such confidentiality. The parties shall take all reasonable steps to ensure that the Confidential Information of Licensor is not used by or made available or furnished or disclosed to any person (other than such party's employees who need to know such Confidential Information for conducting of their ordinary responsibilities on behalf of such party), including, but not limited to, taking at least the steps it takes to protect information, data or other tangible and intangible property of its own that it regards as proprietary or confidential. The parties shall instruct its employees and agents having access to Confidential Information of collaboration regarding the terms and limitations contained in this Agreement.

CHAPTER 7 FORCE MAJEURE

7.1. When the force majeure events happen, the Party affected by force majeure events shall notify the other Party of the same by telex or telegraph as soon as possible, and shall supply to the other Party effective evidential documents by air registered mail within 14 days since the force majeure events.

7.2. If the force majeure events continue for more than 120 days, the parties shall then discuss the execution of the signed agreement.

7.3. Except as expressly provided otherwise herein, any delays in or failures of performance by any party under this Agreement shall not be considered a breach of this Agreement if and to the extent caused by occurrences beyond the reasonable control of the party affected, including but not limited to: acts of God, new regulations or laws of any government; strikes or other concerted acts of workers; fire, floods, explosions; riots; wars; rebellion; and, sabotage, and any performance time under this agreement shall be extended based on the delay time reasonably caused by such events.. The above provisions shall not be used as an excuse for the Joint Entity to delay or substitute for any overdue payment under this agreement.

CHAPTER 8 GOVERNING LAW

8.1. The signing of this cooperation agreement, its validity, interpretation and execution, and the settlement of disputes related to this agreement shall be governed by Chinese laws and have been publicly released. However, if China does not have public laws on specific issues related to this agreement, then refer to general international business practices

8.2. The collaborative work signed in this agreement will be protected by the laws of the People's Republic of China.

CHAPTER 9 DISPUTE RESOLUTION

If a dispute arises in connection with the validity, interpretation or implementation of this Agreement, the parties shall attempt in the first instance to resolve such dispute through friendly consultations. If the parties fail to reach an agreement after consultation, such dispute shall be submitted to the International Arbitration Committee for arbitration actions. The decisions made by the Arbitration Committee shall be the final, and shall be effective and have restrictions to parties with fairness. The place of Arbitration shall be in Hong Kong, China.

CHAPTER 10 MISCELLANEOUS

10.1. Any and all amendments to the clauses in this agreement shall be agreed upon and signed in written documents by all Parties, which shall be considered as integral parts of this agreement and have the same legal effect as this agreement.

10.2. After expiration of this agreement, if there is still unpaid debt by any party, these debts are still effective and are continued obligations to be paid by the party who owes debts to.

10.3. The text of this agreement and its exhibits are all integral parts of this agreement and have the same legal force and effect.

10.4. This agreement is written in English and Chinese version. The communications between Parties shall be conducted in both English and Chinese. Formal notices shall be in written in duplicate, sent by registered air mail. All parties shall ensure that the Chinese version and English version of the agreement, any communication or notice shall be consistent.

10.5. Upon signing this agreement and paying the licensing fee, The Joint Entity will obtain the right of first refusal for the Ii-Key vaccine technology for oncology, infectious disease, and autoimmune diseases. After discussion, Generex's Ii-key's platform license transfer and license fee does not exceed US$50 million

10.6 Any party who intends to publicly disclose any cooperation information requires the prior written consent of the four parties (email).

10.7 E signature

E signature on the agreement is valid.

IN WITNESS WHEREOF, the undersigned parties have caused this Agreement to be executed as of the date first written above by their duly authorized representatives.

Beijing Youfeng International Consulting Co., Ltd 北京优峰国际咨询有限公司

By: _____

Name: _____

Title: Chairman of the Board/President

Date: _____

Generex Biotechnology Corporation

By: _____

Name: _____

Title: Chairman of the Board/President

Date: _____

NuGenerex Immuno-Oncology (a subsidiary of Generex)

是 Generex 的独立上市分公司

By: _____

Name: _____

Title: Chairman of the Board/President

Date: _____

National Institute for Viral Disease Control and Prevention, Chinese Center for Disease Control and Prevention

中国疾病预防控制中心病毒病预防控制所

By: _____

Name: _____

Title: Chairman of the Board/President

Date: _____

Beijing Guoxin Haixiang Equity Investment Partnership (Limited Partnership)

北京国信海翔股权投资合伙企业（有限合伙）

By: _____

Name: _____

Title: Chairman of the Board/President

Date: _____

Exhibit A

Technical Licensing Certificate

1.1 Licensing. Subject to any reserved rights under this Agreement, Party B hereby grants to the Joint Entity a royalty-bearing, non-transferable, sub licensable license to develop, produce and commercialize the Licensed Technology within the Licensed Territory and the Licensed Area based on Party B's Technology as set forth in Section 1.1 of the the Ii-Key Innovative Vaccine Development Agreement (the "Licensing"). Subject to other provisions of this Agreement, the licensing is (a) if Party B owns or is entitled to exclusive licensing of the licensed patent rights and know-how, then Party B will grant an exclusive licensing of such licensed patent rights and know-how to the Joint Entity, and (b) if Party B is entitled to non-exclusive licensing of the licensed patent rights and know-how, then Party B will grant such licensed patent rights and know-how to the Joint Entity on a non-exclusive basis. For clarity, the Licensed Technology herein shall include all inventions, technical improvements, joint improvements related to the licensed technology that are necessary or essential for the development, production or commercialization within the Licensed Territory.

1.2 Licensed Territory. The Licensed Territory shall be limited to Mainland China (shall mean the People's Republic of China, and solely for purposes of this Agreement, including the Hong Kong Special Administrative Region and the Macau Special Administrative Region but excluding the Islands of Taiwan). For the avoidance of doubt, with respect to the sale of such technology in other countries outside the Licensed Territory, Party B agrees to then negotiate separately with the Joint Entity, and the export of such technology involving social public welfare shall not be subject to the restrictions of the Licensed Territory.

1.3 Licensed Aera. The development, production and sales of li-key vaccine technology.

1.4 Term. The Licensing shall be effective as of the date of the Ii-Key Innovative Vaccine Development Agreement and is perpetual and will not be revoked or terminated except for the material breach by the Joint Entity.

1.5 Exclusivity. The Licensing is the sole and exclusive license within the Licensed Territory and the Licensed Area, except for the Joint Entity, no third party (including Party B) has the right to use the Licensed Technology within the Licensed Territory since the effective date of the Licensing.

1.6 Reserved Rights. Except for the rights expressly granted to the Joint Entity under the terms of this Agreement, Party B reserves the right to use the Licensed Technology.

1.7 Sub-licensing. Subject to the terms and conditions of this Agreement, Party B hereby grants to the Joint Entity sub-licensing rights under the Licensing, and the Joint Entity shall have the right to grant sub-licensings to one or more of its Affiliates (the "Joint Entity Sub-licensee"), which sub-licensings shall not exceed the scope of the Joint Entity's rights under this Agreement.

Exhibit B

List of Authorized Intellectual Property Rights

Attached are the provisional patents on the Ii key peptides - there are 33 filed plus the cell epitope, once the testing is done in two weeks, the best 3-5 will be picked out of these patents plus the cell epitope and the 3m adjuvant and then the complete COVID vaccine patents will be filed, the complete COVID vaccine patents plus the attached are all going in the Joint Entity.

File Name:

1) 2020_02_28_EpiVax_Ii_key_Coronavirus_Provisional_Application_FINAL

2) 2020_03_19_EpiVax_Ii_key_Coronavirus_Provisional_Application_FINAL

Scheduling

The implementation of a synthetic vaccine development platform for COVID-19 applications requires the following Tasks.

Select Ii-Key-SARS-CoV-2 Epitope Peptides for Final Vaccine Formulation

to

Advance to Human Clinical Trials

Task 1: Manufacture 33 Laboratory Grade Ii-Key Peptide Vaccines

(The number of epitopes to be determined-see below) (Completed in US)

Party B has produced 33 laboratory-grade Ii-Key peptides for use in screening blood samples of people in the United States. According to the needs of the cooperative research team, Party B will produce more laboratory-grade Ii Key peptides (each small-scale production of about 20 mg) for screening the convalescent blood and serum samples of the entire population

Task 2: Screen Ii-Key-Epitope Peptides against convalescent serum from the all populations (All the population, in US, has completed)

Party B is currently screening the 33 Ii-Key-SARS-CoV-2 peptides against convalescent blood samples from COVID-19 recovered patients at a commercial laboratory and at an academic research institute in the U.S. to evaluate T-Cell activity and ability to bind neutralizing antibodies. The final Ii-Key polypeptide vaccine formulation will be grouped by HLA type.

NOTE: Because the Ii-Key is specific for human HLA complexes and HLA varies across ethnic populations, the Ii-Key-SARS-CoV-2 epitope peptides that work in the U.S. population may not be optimal for the East Asian population. Therefore, following the U.S. blood screening program, analyzing the T-Cell response data, and evaluating the HLA interactions of the Ii-Key-SARS-CoV-2 peptides, the cooperative research team will mutually determine which Ii-Key epitope peptides are optimal for the Chinese population, and conduct additional in-vitro T-Cell assays using convalescent blood samples from patients who have recovered from COVID-19 to develop vaccines to be used in China. Party B will provide technical solutions for T cell detection to the cooperative research team.

Task 3: Conduct Immunogenicity study of Ii-Key-Epitope Peptides in the DR4 humanized transgenic mouse model with Human HLA (complete by US and China team)

NOTE: Because the Ii-Key is specific for human HLA complexes to activate human CD-4 responses, animals will not respond the same as humans to Ii-Key Peptide Vaccines. Human Ii-Key does not bind to animal MHC complexes to activate animal CD-4 responses. Therefore, transgenic animal models with human immune cells are needed for immunogenicity trials in animals. Party B has plans to evaluate the U.S. formulation of the Ii-Key-SARS-CoV-2 vaccine in mouse immunogenicity studies using the DR4-Transgenic mouse model. Party B will provide the study report to Party C for filing with the NMPA. If the pre clinical study reports are not sufficient for the NMPA, Party C agree to conduct any and all pre-clinical and immunogenicity studies required by the NMPA to enable human clinical trials in China.

Task 4: Manufacture GMP Ii-Key-SARS-CoV-2 Vaccine

Manufacture medium-scale, GMP-grade multivalent Ii-Key-SARS-CoV-2 Peptide Vaccine for Phase I and Phase II human clinical trials - 10 to 100 g each peptide depending on final protocol.

Milestone: Manufacture, fill & finish Ii-Key-SARS-CoV-2 Peptide Vaccine to meet standards of the NMPA for Phase I and Phase II human clinic studies

Task 5: Phase I and Phase II Human Clinical Trials (China and the U.S. proceed simultaneously)

Early stage clinical trials to evaluate the safety and dose of the final Ii-KeySARS-Co V-2 Peptide Vaccine in health adults (18 - 55 years old). Single or with a booster shot 14-21 days from initial dose, ascending dose study of peptide administered via sub-cutaneous injection with and without adjuvant. Party B will provide The Joint Entity with the currently planned clinical study design and protocol for the Phase I and II clinical trials upon technology transfer. The final protocol will be determined by the regulatory requirements of the NMP A.

Milestone I: The Phase I study is designed to allow selection of the optimal dose of Ii-Key-SARS-CoV-2 Peptide Vaccine (and adjuvant) that produces the strongest, yet safe, immunological response.

Milestone II: The Phase II study is designed to provide sufficient safety data to enable Phase III human clinical trials of the Ii-Key-SARS-Co V-2 vaccine to evaluate the efficacy and safety in the all populations.

Task 6: Manufacture large-scale Ii-Key-SARS-CoV-2 peptide vaccine (In China)

Manufacture large-scale, GMP production of a multivalent the Ii-KeyÂSARS-CoV-2 Peptide Vaccine for Phase III human clinical trials - 1 KG each peptide.

Milestone: NMPA approval to manufacture Ii-Key-SARS-CoV-2 Peptide Vaccine for Phase III human clinic studies and commercial use

Task 7: Conduct Phase III clinical studies of Multivalent Ii-Key Peptide Vaccine in Large Population (26 weeks - 3 years) (Territories and countries where have a large Asian population, such as California and New York)

Conduct Large-scale immunization study in certain number of volunteers (number to be decided by regulatory authorities) to evaluate the safety, immune activation, and efficacy of the Ii-Key-SARS-CoV-2 Peptide Vaccine. The protocol will be designed to evaluate the safety and effectiveness of the vaccine to protect people from COVID-19 disease.

Milestone: Meet the product requirements of NMPA and the Department of Immunization of the National Health Commission to approve the production and sale of Ii-Key-SARS-CoV-2 peptide vaccine products.