

Generex Biotechnology Subsidiaries NuGenerex Immuno-Oncology and NuGenerex Diagnostics Working to Address the Coronavirus Pandemic and Emerging Risk of Avian Flu Using li-Key Peptide Vaccines

- NuGenerex Immuno-Oncology's li-Key technology is clinically proven to activate the immune system against numerous viruses including H5N1 avian influenza virus
- li-Key peptide vaccines offer real potential for a cost effective, rapid response vaccine that can provide immunity to the 2019-nCoV and Avian influenza (Bird Flu)
- NuGenerex Diagnostics using peptides to develop a rapid test for 2019-nCoV in respiratory and blood samples using its proprietary NGDx Express II rapid diagnostic technology

MIRAMAR, FL, February 6, 2020 - Generex Biotechnology Corporation (www.generex.com) (OTCQB:GNBT) (<http://www.otcm Markets.com/stock/GNBT/quote>) today announced that the company is working with third party groups and government agencies to reactivate the previously robust research and development to generate li-Key peptide vaccines against pandemic viruses. The patented NuGenerex Immuno-Oncology (Formerly Antigen Express) li-Key technology uses synthetic peptides that mimic essential protein regions from a virus that are chemically linked to the 4-amino acid li-Key to ensure robust immune system activation. In particular, The li-Key ensures potent activation of CD4+ T cells, which in turn facilitates antibody production to ward off infection. This li-Key modification can be applied to any protein fragment of any pathogen to increase the potency of immune stimulation (up to 100-fold) while maintaining absolute specificity of response. The peptides and li-Key are made from naturally occurring amino acids, ensuring an excellent safety profile for li-Key peptide vaccines. Also, there are many companies with existing facilities that can make clinical-grade synthetic peptide vaccines in hundred-kilogram quantities, providing a scalable, economically feasible rapid-response vaccine to pandemic viruses; a kilogram of li-Key peptide vaccine would be enough to vaccinate roughly 1 million people. Unfortunately, when these pandemics fade out, everyone forgets about them until the next one. When the SARS scare waned, we focused all of our resources on developing li-Key immunotherapeutic peptide vaccines for cancer. Generex has been on the forefront of immunotherapy using our proprietary li-Key peptide vaccine technology.

NGIO has extensive experience with the design of viral and cancer vaccines. We designed a series of vaccine peptides for the potentially pandemic H5N1 avian influenza virus that were tested in over 120 volunteers as part of a Phase I trial. The vaccine peptides were safe, well tolerated, and generated a specific immune response as designed.

In addition to the H5N1 study, peptides with the same li-Key modification have been used in multiple clinical trials in patients with early stage cancer, including breast and prostate cancers. To date, all li-Key peptide vaccine studies demonstrated excellent safety as well as specific and

long-lasting immune responses. Avian influenza has recently been identified in animals in Wuhan, China (the region where the coronavirus started), so the li-Key-H5N1 vaccine, with human safety data is ready to be deployed in the clinical setting to inoculate people against another potential pandemic.

Based on our experience from the H5N1 virus li-Key peptide vaccine program, we have developed a strategy to design, screen and identify vaccine peptides to any novel pathogenic virus within 5 months, and we are initiating efforts to develop a vaccine against 2019-nCoV.

About our Rapid Diagnostic Testing Technology:

NuGenerex Diagnostics (NGDx) has developed the **Express II**, an innovative, patent-pending, point-of-care rapid diagnostic platform. The proprietary **Express II** kit design is complex enough to detect a wide range of analytes including antigens, antibodies, or protein biomarkers that are found in infectious diseases, cancer, metabolic diseases and a host of other medical conditions. Though complex, the **Express II** is simple enough to be performed in the physician's office or even at home by consumers.

Using the **Express II** platform, NGDx has developed point-of-care rapid diagnostic tests for HIV, Hepatitis B Hepatitis C, Tuberculosis, Syphilis and three Malaria-specific assays. Our syphilis assay, The **Express II Syphilis Treponemal Assay**, which has been approved for commercialization in Europe through the European CE Marking regulatory process, is a rapid point-of-care diagnostic assay for the detection of syphilis antibodies in primary and secondary syphilis with an accuracy equal to or better than standard laboratory assays for syphilis, with sensitivities and specificities of over 99%.

The **Express II** diagnostic platform has major advantages over other point-of-care devices because of its simplicity of use, which include fewer steps of operation, the elimination of loops or pipettes for transferring samples, the elimination of unnecessary sample pickup pads, and its ability to be utilized in office settings, remote field use and for individual in-home use directly by consumers who can conduct the test by themselves in privacy. The results of any assay conducted using the **Express II** platform are available in 15-20 minutes, allowing clinical and therapeutic decisions to be made immediately and, if positive, appropriate patient counseling can be initiated on site.

Currently, NGDx is initiating a project to adopt the **Express II** platform in the development of a diagnostic point-of-care test for the rapid diagnosis of the novel Wuhan Coronavirus (2019 nCoV) infection which has been declared a worldwide public health emergency by the World Health Organization. This test will allow the detection of the Wuhan Coronavirus directly in respiratory samples taken from the nose and throat of individuals and can be used for screening of travelers at national border entry points, or for direct diagnosis of suspected infected persons with symptoms, with results available in 15-20 minutes. It requires minimum training and can be used by national security agents, airline employees and any other appropriate authorized individual in all commercial and medical settings.

“Sometimes a small biotech company has to work harder to be noticed for their valuable work. Generex has a wealth of valuable technology that has been built with over \$50 million in dollars in research and development expenditures,” said Joseph Moscato, President & CEO of Generex Biotechnology. “We had a large and successful infectious disease program a decade ago when our subsidiary NuGenerex Immuno-Oncology (then Antigen Express) was developing li-Key hybrid vaccines against a range of pathogens including HIV, bird flu, swine flu, Ebola, and SARS, another coronavirus. Our technology is based on old-fashioned technology that for 100 years has been used to develop vaccines with antigen proteins and peptides from pathogens. Our li-Key supercharges peptide vaccines to activate the immune system, and because we make synthetic peptides, they are cheaper, safer, and easier to use than the research stage vaccines that are currently being funded in response to this coronavirus outbreak. Plus, we are further along than those other companies, having significant human safety data that will allow us to test our vaccines in human clinical trials.

We have vaccinated over 400 people with li-Key vaccines to prove their safety and their effectiveness in activating the immune response against viral infections. Additionally, our experience with antigen/epitope prediction and peptide chemistry translates directly to the development of new, point-of-care rapid diagnostic tests using our patent pending Express II diagnostic kits. With the 2019-nCoV coronavirus pandemic spreading across the globe, we are offering our li-Key peptide technology to partners and governments seeking a real solution rather than a hopeful research project. Our li-Key peptide vaccines can be rapidly deployed for population vaccination as they have been proven safe in humans. Our peptide vaccines are easily and economically manufactured at commercial scale using standard solid-state peptide chemistry and currently available facilities. Plus, we have identified a potential partner that has identified a series of epitopes from the 2019-nCoV virus sequence, so we are positioned to rapidly develop and test 2019-nCoV specific li-Key-hybrids vaccines. We welcome inquiries from interested parties that have proprietary antigen/epitope products that can be linked with the immune system activating li-Key to build new vaccines against this global threat. Governments, health ministries, and large pharmaceutical companies need to take a look at our data from all of our research and clinical development work on pandemic vaccines. See how far along we are; ask the questions; and partner with us as on preventing the spread of the 2019-nCoV virus. The world needs a vaccine, and we see our li-Key technology as a viable solution if funded and provided the necessary resources to develop and commercialize a vaccine for all.”

About Generex Biotechnology Corp.

Generex Biotechnology is an integrated healthcare holding company with end-to-end solutions for patient centric care from rapid diagnosis through delivery of personalized therapies. Generex is building a new kind of healthcare company that extends beyond traditional models providing support to physicians in an MSO network, and ongoing relationships with patients to improve the patient experience and access to optimal care.

NuGenerex Immuno-Oncology (formerly Antigen Express), a subsidiary of Generex Biotechnology, is a clinical stage oncology company developing immunotherapeutic peptide vaccines based on the CD-4 T-Cell activation platform, li-Key. NuGenerex Immuno-Oncology (NGIO) is being spun out of Generex as a separate, independent public company to advance the platform li-Key technology, particularly in combination with the immune checkpoint inhibitors. NGIO is currently engaged in a Phase II clinical trial of its lead cancer immunotherapeutic vaccine AE37 in combination with pembrolizumab (Merck's Keytruda®) for the treatment of triple negative breast cancer.

Cautionary Note Regarding Forward-Looking Statements

This release and oral statements made from time to time by Generex representatives in respect of the same subject matter may contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements can be identified by introductory words such as "expects," "plan," "believes," "will," "achieve," "anticipate," "would," "should," "subject to" or words of similar meaning, and by the fact that they do not relate strictly to historical or current facts. Forward-looking statements frequently are used in discussing potential product applications, potential collaborations, product development activities, clinical studies, regulatory submissions and approvals, and similar operating matters. Many factors may cause actual results to differ from forward-looking statements, including inaccurate assumptions and a broad variety of risks and uncertainties, some of which are known and others of which are not. Known risks and uncertainties include those identified from time to time in the reports filed by Generex with the Securities and Exchange Commission, which should be considered together with any forward-looking statement. No forward-looking statement is a guarantee of future results or events, and one should avoid placing undue reliance on such statements. Generex undertakes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise. Generex claims the protection of the safe harbor for forward-looking statements that is contained in the Private Securities Litigation Reform Act.

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