

Generex Subsidiary NGIO Advances COVID-19 Vaccine Program with the Manufacturing of Patent-Pending li-Key-SARS-CoV-2 Peptides

- NuGenerex Immuno-Oncology (NGIO) is focused on modulation of the immune system to develop li-Key peptide vaccines for the treatment and prevention of cancer and infectious diseases
- NGIO advancing li-Key peptide vaccines against the SARS-CoV-19 pandemic
- li-Key Peptides Advancing to Clinical Laboratory “Ex-Vivo” Human Immune System Screening Program
- NGIO’s AE37 Phase II breast cancer trial peer review data just published showing significantly positive results at 10 years with additional benefit to late stage patients https://storage.googleapis.com/wzukusers/user-26831283/documents/c8e4b2bab3d647968f576008791340f3/Brown2020_Article_ProspectiveRandomizedSingle-bl.pdf

MIRAMAR, FL, May 22, 2020 - Generex Biotechnology Corporation (www.generex.com) (OTCQB:GNBT) (<http://www.otcm Markets.com/stock/GNBT/quote>) today announced that their COVID-19 vaccine program has reached a milestone with the manufacturing of 33 li-Key-SARS-CoV-2 peptides using antigenic epitopes predicted by computational vaccinology algorithms. Provisional patent applications have been filed for these li-Key-SARS-2 peptides, protecting intellectual property rights for Generex and COVID-19 vaccine products based on the viral sequences with li-Key. Once the peptides pass Quality Assurance testing, they will be shipped to the clinical laboratories conducting the “Ex-Vivo” Human Immune System Screening Program using blood and plasma samples from patients who have recovered from COVID-19 that have already been collected and stored for the screening program. The unique ex-vivo human immune system studies with convalescent blood samples will provide the data to select the best li-Key-SARS-CoV-2 peptides for a “Complete Vaccine” that promotes B-Cell production of neutralizing antibodies and activates CD4+ T-Cell responses (TH1) that promote immune memory and potential long-term protection from coronavirus infection. Additionally, the vaccine screening program will address the safety of the li-KeyRS-CoV-2 peptides using a validated in-vitro assay that models the dangerous cytokine storm associated with COVID-19.

Joseph Moscato, Generex President & CEO stated, “We are excited to continue advancing the COVID-19 vaccine program, taking another step to unlocking the value and true potential of our immuno-oncology assets. Not only are we moving ahead with our coronavirus vaccine program, but we are also achieving milestones in our oncology program, as demonstrated by the recently published results of the Phase IIb clinical trial of the li-Key-HER2 peptide vaccine AE37 for the prevention of recurrent breast cancer. The trial demonstrated that patients with advanced breast cancer and low levels of HER2/neu who were treated with AE37 immunotherapy had a statistically significant improvement in disease free survival over 10 years.

The statistically significant and positive AE37 clinical trial results validate our continued work with the National Surgical Adjuvant Bowel & Breast Project (NSABP) to develop AE37 in combination with pembrolizumab (Merck’s Keytruda®) for the immunotherapeutic treatment of triple negative breast cancer. Trial enrollment was slowed recently due to the coronavirus, but we are

expanding enrollment efforts, and we have added the world-famous Cleveland Clinic as one of our NSABP sites. We expect enrollment to speed up with these positive results as the coronavirus pandemic subsides. Also, in the next quarter we are planning to initiate a trial of AE37 in combination with checkpoint inhibitor for the immunotherapeutic treatment of bladder cancer with investigators at MD Anderson Cancer Center, and we have begun to plan a trial of the li-Key-GP100-TYR peptide vaccine for the treatment of melanoma.”

Mr. Moscato continued, “Over the last two months, Generex has responded to the COVID-19 emergency using our technology platform to work to develop an li-Key-SARS-CoV-2 vaccine. We have licensed coronavirus epitope sequences and we are in the process of manufacturing li-Key peptides that will be screened against blood samples from patients who recovered from COVID-19 in an “Ex-Vivo” human study. We have established a plan to test the li-Key peptides in a complete immunology screening program to evaluate their ability to modulate CD4+ and CD8+ T-Cell responses. Additionally, we will select peptides based on their ability to bind neutralizing antibodies that provide immunity to the virus. We will be testing the antibodies in virus neutralization assays to select the peptides for the vaccine, and in a cellular assay that models the cytokine storm in order to eliminate peptides that may cause an adverse immunologic response. With the results from our broad and proprietary immunological screening program, which we anticipate having in June, we will have an early indication of the immunologic efficacy and safety of an li-Key-SARS-CoV-2 peptide vaccine before our clinical trials even start. These Ex-Vivo human immune system studies are designed to enable the development of a “Complete Vaccine” to provide immunity from COVID-19 without the cytokine storm potential that is so worrisome for coronavirus vaccines developed with whole virus, recombinant protein vaccines, and nucleic acid vaccines that do not have the specificity of li-Key peptide vaccines.”

In the coming weeks Generex will be announcing a shareholder’s conference call to give a complete operations update.

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 CD4 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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