Generex Biotechnology Initiates Peptide Manufacturing for Ii-Key- SARS-CoV-2 Peptide Vaccine Against the COVID-19 Pandemic

- Submitted proposal to BARDA for start-to-finish funding to develop an approved, commercial Ii-Key peptide vaccine against the SARS-CoV-2 coronavirus
- SARS-CoV-2 epitope identification and selection completed
- Initiated GLP manufacturing of synthetic Ii-Key-SARS-CoV-2 peptides for screening in "Ex-vivo" human trial in blood samples from COVID-19 convalescent (recovered) patients
- Obtained letters of support for BARDA Application from scientific partners, prestigious universities, major contract manufacturers, and a prominent CRO that will manage the international regulatory effort and the proposed end-to-end clinical program

MIRAMAR, FL, May 4, 2020 - Generex Biotechnology Corporation (www.generex.com) (OTCQB:GNBT) (http://www.otcmarkets.com/stock/GNBT/quote) today announced that the company has submitted a contract proposal to BARDA to develop a vaccine against the SARS-CoV-2 coronavirus using the patented Ii-Key vaccine technology. Following the BARDA application, and in an effort to rapidly respond to this pandemic emergency, Generex has now initiated the manufacturing of synthetic peptides with Ii-Key linked to SARS-CoV-2 epitopes predicted by computational vaccinology algorithms. These Ii-Key-SARS-CoV-2 peptide epitopes, which contain target amino acid sequences from the virus, will be screened against blood samples collected from COVID-19 convalescent (recovered) patients to select those Ii-Key peptides that activate the immune system to fight the coronavirus infection. The blood screening program, which is scheduled to begin to begin shortly, incorporates T Cell Assays, B Cell Assays, Antibody and Virus Neutralization tests, and a novel in-vitro "cytokine storm" cellular assay to identify the Ii-Key-SARS-CoV-2 peptides vaccines most likely to stimulate the T-Cell (CD4 and CD8) response, modulate appropriate immune system responses to minimize potential for dysregulated cytokine-related inflammation, stimulate a neutralizing antibody response, and provide a broad-spectrum coverage for the vast majority of people. This strategy leverages Ii-Key technology to develop a "Complete Vaccine" that has the potential to induce the likelihood of protective immunity with long-lasting immunologic memory against SARS-COV-2 in a highly specific manner to ensure safety. The most important aspect of this ex-vivo human trial approach is that we can select the right peptides for Ii-Key vaccine peptides that will limit the risk of off-target immune responses that may lead to a cytokine storm, and we find the answers very early in the development process before we vaccinate any human volunteers.

Generex CEO, Joseph Moscato said, "We have been working diligently over the last two months to rapidly respond to the coronavirus pandemic, because our Ii-Key peptide technology offers true promise for an effective and safe COVID-19 vaccine. Highlighting the potential for our Ii-Key-SARS-CoV-2 "Complete Vaccine", Generex has obtained letters of support from key, industry leading partners to provide their expertise, experience, facilities and infrastructure for the development and manufacturing of an Ii-Key-SARS-COV-2 vaccine. We have contracted PPD, a recognized leading CRO to provide comprehensive, turnkey clinical and regulatory services, including regulatory submissions, site preparation, clinical testing, data management, protocols

and reports required to maximize the speed and path to licensure. Additionally, we are planning GMP vaccine production with industry leaders in GMP peptide synthesis, including Polypeptide Laboratories (the manufacturers of our AE37 Ii-Key-HER2 immuno-oncology product), Bachem, and Corden Pharma who are on board to provide clinical trial material and kilogram scale commercial manufacturing. We also have support from international leaders, Ajinomoto and Thermo-Fisher for fill/finish and quality control, ensuring both capacity and redundancy to deliver on large scale vaccination requirements. Further, we have obtained a letter of support from 3M to evaluate the use of their new vaccine adjuvant in the formulation of the Ii-Key peptide vaccines for the comprehensive clinical program that was outlined in our proposal."

Mr. Moscato continued, "Because Generex' subsidiary NuGenerex Immuno-Oncology has a long history of developing the Ii-Key peptide vaccine technology to rapidly respond to potential pandemic threats, we have been able to rapidly mobilize our efforts to help respond to the COVID-19 global pandemic. And, as shown in the recently published positive results from our Phase II trial of AE37 in the prevention of breast cancer recurrence in hard to treat patients, the Ii-Key activates the T-Cell response against the HER2 antigenic epitope to which it is attached. The authors point out the benefit of such a complete immune response combining CD8+ and CD4+ activation may not only induce an immediate cell mediated cytolytic response versus tumor antigens but may also induce T-Helper cell mediated long-term immunity to protect against tumor recurrence. The activation of a complete immune response against coronavirus antigens modulated by the Ii-Key is what sets us apart from others in the field and makes us confident in our plans to deliver a COVID-19 vaccine with our Ii-Key-SARS-CoV-2 peptide vaccine development program. We will keep our investors informed as the development progresses."

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, Ii-Key. NuGenerex Immuno-Oncology (NGIO) is being spun out of Generex as a separate, independent public company to advance the platform Ii-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.

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This release and oral statements made from time to time by Generex representatives in respect

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