# Generex Inks \$50 Million Licensing Deal with China Partners on the Cooperative Development of the li-Key Vaccine Platform

- \$50 million licensing deal for the li-Key platform to develop vaccines for infectious diseases and cancer
- Deal includes first contract for Ii-Key- SARS-CoV-2 vaccine against COVID-19 in China with a \$5 million upfront licensing fee, 100% funding for manufacturing, development and commercial registration and a \$20 million success fee for approval Ii-Key- SARS-CoV-2 vaccine in China
- Royalty payments for COVID vaccine with billion-dollar royalty potential
- Framework agreement for the development of additional li-Key vaccines for cancer & infectious diseases under separate licensing deals with fees, milestones, and royalties on sales
- An 8K will be filed on the contract today

MIRAMAR, FL, November 18, 2020 - Generex Biotechnology Corporation (<u>www.generex.com</u>) (OTCQB:GNBT) (<u>http://www.otcmarkets.com/stock/GNBT/quote</u>) is pleased to announce that the company has closed a \$50 million Licensing and Development Agreement with a consortium of partners in China for the li-Key vaccine platform technology from Generex subsidiary NuGenerex Immuno-Oncology (NGIO).

Under the terms of the deal, Generex will receive a licensing fee of up to \$50 million for the exclusive use of the li-Key vaccine platform for infectious disease and cancer in China and its territories. For each product developed using the li-Key technology under the platform license, Generex will receive an upfront payment, full funding for product development, regulatory approval, and commercialization in China, a success fee upon product approval, and a royalty to be determined on a case-by-case basis.

The agreement incorporates the first Ii-Key platform project for the development and commercialization of the Ii-Key-SARS-CoV-2 coronavirus vaccine in China, with a \$5 million upfront licensing fee, 100% funding for manufacturing, development and commercial registration, a \$20 million success fee for approval Ii-Key- SARS-CoV-2 vaccine in China, and royalty payments for COVID vaccine sales in China with the potential to reach several billion dollars. The Agreement incorporates provisions to advance the development of other Ii-Key vaccines for infectious diseases and cancer under separate contracts that are currently being finalized. The partnering groups have been previously announced as part of the company's Framework Agreement. Generex is filing an 8K with the SEC, including details on the deal, as well as copies of the final agreements.

"The Ii-Key-SARS-CoV-2 vaccine is designed as a "Complete Vaccine" that has the potential to induce the T-Cell and antibody immune responses in a highly specific manner that can provide protective immunity with long-lasting immunologic memory against SARS-CoV-2 and other pandemic threats like swine flu", said Richard Purcell, Executive Vice President of R&D for Generex and NuGenerex Immuno-Oncology. "We have a proprietary approach to vaccine development that enables us to understand how our Ii-Key vaccines regulate the proper immune response because of the specificity of our Ii-Key-SARS-CoV-2 epitopes. We are able to generate a detailed immune activation profile of our Ii-Key vaccine candidates by screening blood samples from COVID-19 recovered patients. This unique ex-vivo human study approach enables us to know, prior to even Phase I clinical trials, whether the Ii-Key epitopes will activate CD4+ T helper cell and CD8+ T lymphocytes without activating the detrimental Th2 response that can lead to

disease enhancement and the cytokine storm. Further, we can screen the patient samples for antibody binding to our li-Key vaccine candidates to ensure that our li-Key vaccines contain the appropriate coronavirus epitopes for a Complete Vaccine that activates targeted immune response. We are very happy with our blood screening data to date, as numerous li-Key vaccine candidates have been shown to activate the Th1 T-Helper response (as measured by gamma interferon) and the CD8+ response (as measured by Granzyme B) with no indication of Th2 activation (as measured by IL-5). Plus, we have positive antibody binding from patient serum. So, as we move toward the clinic, we already have data to demonstrate the potential for our li-Key technology to deliver a safe and targeted vaccine that is designed to limit off-target immune responses that can lead to the complications of COVID-19."

Generex CEO, Joseph Moscato said, "Our partners in China understand the science and the power of the li-Key technology for the regulation of the immune system to develop safe and effective vaccines for infectious disease and cancer, and with this agreement, we cement our partnership to realize the full potential of our li-Key vaccine technology. With this partnership, Generex is perfectly positioned in China to deploy the li-Key platform as the leading technology for rapid response to emerging infectious diseases. We look forward to working in mutual collaboration with our partners to advance the li-Key vaccine development platform."

Mr. Moscato continued, "This is probably the biggest deal Generex could even imagine and we are all too happy to be partners with these acclaimed institutions to help China and the world alleviate the threat of pandemic infections. Plus, we now have the ability to advance our li-Key cancer platform to realize the full potential of Ii-Key immunotherapies to target tumor biomarkers across oncology indications. The Ii-Key-SARS-CoV-2 vaccine is the first product under this Ii-Key platform license, and in the coming days, we will announce agreements for additional Ii-Key vaccine development projects as well as licensing deals for other products from the NuGenerex family of companies."

# 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.

### About NuGenerex Immuno-Oncology

NuGenerex Immuno-Oncology, a subsidiary of Generex Biotechnology, is a clinical stage oncology company developing immunotherapeutic peptide vaccines for cancer and infectious disease based on the CD4 T-Cell activation platform, li-Key. NuGenerex Immuno-Oncology (NGIO) has been spun out of Generex as a separate public company to advance the platform li-Key technology, particularly in combination with the immune checkpoint inhibitors for the treatment of cancer. 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. The company has also turned its li-Key technology on infectious disease, responding to the coronavirus pandemic with a SARS-CoV-2 vaccine development program.

# **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.

### **Generex Contact:**

Generex Biotechnology Corporation

Joseph Moscato 646-599-6222

Todd Falls 1-800-391-6755 Extension 222 investor@generex.com