Generex Signs Binding Licensing & Research Agreement with Bintai Kinden to Advance the Clinical Development & Commercialization of Ii-Key-SARS-CoV-2 Coronavirus Vaccine for Malaysia

- Bintai Kinden Corporation Berhad (www.bintai.com.my) is an investment holding company headquartered in Malaysia with operations throughout South-East Asia, China, and the Arabian Gulf Region
- Upfront licensing fee of $2.5 million
- 100% funding for development, manufacturing and commercial registration of Ii-Key-SARS-CoV-2 prophylactic vaccine against COVID-19 in Malaysia
- Milestone payments totaling $17.5 million upon approval by Malaysian Ministry of Health
- Contracted royalty of $3 - $4.50 per dose of vaccine
- Potential $150 million in GNBT revenues for vaccine sales in Malaysia
- Potential to expand the partnership and development agreement in Australia, New Zealand, and the global HALAL markets

MIRAMAR, FL, September 18, 2020 Generex Biotechnology Corporation (www.generex.com) (OTCQB:GNBT) (http://www.otcmarkets.com/stock/GNBT/quote) is pleased to announce that the company and Bintai Kinden Corporation of Malaysia have signed an addendum binding the terms of the previously signed Memorandum of Understanding for the development and commercialization of the Ii-Key-SARS-CoV-2 coronavirus vaccine.

Under the terms of the Addendum, Bintai and Generex will finalize the legal and contractual documentation for the contract, partnership, and licensing & research agreement, and Bintai will pay Generex an up-front licensing fee of $2.5 million within two weeks. Additionally, Bintai will pay 100% of the funding required for the commercial development of the Ii-Key-CoV-2 vaccine including laboratory work, manufacturing, regulatory filings and the clinical development program for regulatory approval of the vaccine in Malaysia. Also, upon approval of the Ii-Key-CoV-2 vaccine in Malaysia, Bintai will pay Generex a $17.5 million milestone payment and Generex will earn royalties on sales of the vaccine equal to $3 per dose on government sales and $4.50 per dose in the private sector. Further, under this new Addendum, Bintai will have the right of first refusal for the Ii-Key-SARS-CoV-2 vaccine in Australia, New Zealand, and the global HALAL markets, particularly in Southeast Asia.

Under terms of the deal, Generex and Bintai have agreed to collaborate and have developed a strategy towards the rapid development of the Ii-Key-CoV-2 vaccine for Malaysia. As part of that strategy, Generex has identified a local CRO, Jigsaw Clinical Research Solutions (https://www.jigsawclinical.com/), managed by U.S. industry veteran, Jeffrey Yablon who has decades of experience in clinical development and regulatory affairs, and has established Jigsaw as the premier Malaysian CRO.

Generex CEO, Joseph Moscato said, “We want to thank our partners at Bintai for their commitment to develop our Ii-Key-SARS-CoV-2 “Complete Vaccine” against COVID-19. Our Ii-Key vaccine platform has always been about activation of the cellular immune system pathway via Ii-Key, which imparts long term memory through T-Helper cells. Our Ii-Key-SARS-CoV-2 vaccine strategy combines the Ii-Key T-Cell response with B-Cell epitopes that activate the humoral (antibody) response to deliver a Complete Vaccine for short and long-term protection from COVID-19. The Ii-Key platform has demonstrated that AE37, our Ii-Key-HER2 vaccine provides long-term immune memory with cellular responses active for three years in prostate cancer[1], and statistically significant benefit in disease free survival for breast cancer patients with advanced disease and low HER2 expression[2]. Immunologic memory is the key to providing a real solution for COVID-19.

With this licensing and research agreement being finalized, we can unlock the true potential of the Ii-Key technology to provide a safe and effective vaccine to stop the SARS-CoV-2 pandemic, and to provide the long-term immune system memory needed to protect the population. Our plan is collaborative, combining U.S. and Malaysian operations to advance our Ii-Key vaccine through the clinical and regulatory process in Malaysia to eventually transfer the manufacturing to Malaysia for local production, leveraging Bintai’s expertise in industrial engineering and construction. We have initiated the blood screening program using convalescent blood and serum for COVID-19 recovered patients to select Ii-Key-SARS-CoV-2 epitopes that will comprise the final vaccine formulation, after which we will initiate GMP manufacturing for Ii-Key-SARS-CoV-2 vaccine clinical trial supply.”

Mr. Moscato continued, “I would like to personally thank the Bintai organization for their belief in Generex and commitment to develop a safe, effective, and universal vaccine against SARS-CoV-2 for the benefit of Malaysia, and we look forward to accelerating our COVID-19 vaccine program together.”

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, Ii-Key. NuGenerex Immuno-Oncology (NGIO) has been spun out of Generex as a separate public company to advance the platform Ii-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 Ii-Key technology on infectious disease, responding to the coronavirus pandemic with a SARS-CoV-2 vaccine development program.

About Bintai Kinden

With over 40 years of specialist engineering and construction experience, Bintai's unique combination of extensive regional experience and local knowledge has made them the region's international contractor of choice. Headquartered in Malaysia, Bintai Kinden has expanded operations regionally throughout South-East Asia, China and the Arabian Gulf region.

As multi-disciplined, building and industrial service engineers and specialists, Bintai works in all the major market sectors, from commercial buildings to industrial complexes, designing, installing and commissioning systems that include the full range of engineering services.

Looking beyond today's frontiers, Bintai Kinden is confident that it has the resources, technical expertise and progressive mindset to consolidate its position globally. The integration of research, management, marketing and sales that transcends organizational borders enables Bintai Kinden to capitalize on synergistic potential and benefits of scale.

References

[1]Perez et al. Cancer Immunol Immunother (2013) 62: 1599-1608
[2]Brown et al Breast Cancer Research and Treatment. 22 April 2020.

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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

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