NuGenerex Immuno-Oncology Announces Closing of a Licensing & Distribution Agreement with Bintai Kinden to Advance the Clinical Development & Commercialization of Ii-Key-SARS-CoV-2 Coronavirus Vaccine for Global Markets

- Bintai Kinden Corporation Berhad (www.bintai.com.my), an investment holding company headquartered in Malaysia will fund the U.S. Clinical Trials for the Ii-Key-SARS-CoV-2 vaccine against COVID-19
- NuGenerex Immuno-Oncology has received the upfront licensing fee of $2.625 million
- Bintai obtains the exclusive license to distribute the Ii-Key-SARS-CoV-2 vaccine in Southeast Asia, including Malaysia, Vietnam, Indonesia, and the Philippines
- Bintai receives an option with first right of refusal for distribution in Australia and New Zealand
- Bintai will provide 100% funding for U.S. clinical development, manufacturing and commercial registration of Ii-Key- SARS-CoV-2 prophylactic vaccine against COVID-19 in international markets
- Price set at $3 per dose for governments and $4.50 on commercial sales
- Potential $1 billion in GNBT revenues for vaccine sales in Southeast Asia

MIRAMAR, FL, October 7, 2020 NuGenerex Immuno-Oncology (NGIO), a subsidiary of Generex Biotechnology Corporation (www.generex.com) (OTCQB:GNBT) (http://www.otcmarkets.com/stock/GNBT/quote) is pleased to announce the closing of a Licensing & Distribution Agreement with Bintai Kinden Corporation of Malaysia for the development and commercialization of the Ii-Key-SARS-CoV-2 coronavirus vaccine. Under the terms of the Agreement, Bintai will have an exclusive license to distribute the Ii-Key-SARS-CoV-2 vaccine in Southeast Asia, including Malaysia (pop. 32.4 million), Vietnam (pop. 95.5 million), Indonesia, (pop. 69.4 million) and the Philippines (pop. 106.7 million). Additionally, Bintai has been given an option, with right of first refusal for distribution in Australia (pop. 25.5 million) and New Zealand (pop. 4.8 million) using its extensive connections to secure contracts in the region.

In exchange for the license and distribution exclusivity, Bintai has paid an up-front licensing fee of $2.625 million and has committed to funding 100% of the commercial development costs for the Ii-Key-CoV-2 vaccine including laboratory and pre-clinical work, GMP manufacturing in the U.S., U.S. and global Phase I, Phase II, and Phase III clinical trials, and all clinical and regulatory work required for approval in each of the licensed Australasian countries.

NGIO will earn $3 per dose on sales to governments and $4.50 on commercial sales. Targeting a population of nearly 300 million people, the potential revenues for NGIO exceed $1 billion.

Generex CEO, Joseph Moscato said, “With the closing of this Licensing and Distribution Agreement, we have secured the funding to complete the clinical development and regulatory work we need for approval of the Ii-Key- SARS-CoV-2 vaccine. Under the terms of the final agreement, we will conduct our Ii-Key-SARS-CoV-2 vaccine clinical trials here in the Unites States, and the U.S. data will support regulatory filings and commercialization in Southeast Asia that

includes nearly 300 million people. The agreement allows NGIO to maintain its full, global intellectual property and manufacturing rights, and provides Bintai with exclusive distribution rights in the region thereby leveraging both company's strengths for a truly successful partnership that could be worth over $1 billion in licensing and royalty payments to NGIO and Generex, the parent company. Plus, with Bintai's connections in Australia and New Zealand, we hope to expand our exclusive distribution agreement in these countries, which will bring additional licensing and royalty fees to NGIO and Generex."

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 the world. As we prepare to launch the clinical trial program for our Ii-Key-SARS-CoV-2 with a target date in early 2021, we are happy to announce plans to develop our vaccine for the benefit of the pediatric population – adolescents, children and infants – who have been neglected by other vaccine development efforts. Given the demonstrated safety profile of our other Ii-Key vaccines that has been recognized by the FDA, and upon advice from our KOL advisors, we believe that our Ii-Key peptide vaccine technology can fill the unmet medical need and offer a better approach to developing a COVID-19 vaccine that can be safely and confidently used not only in adults, but also in children. Especially on the safety front, we are confident that our highly specific and targeted Ii-Key-SARS-CoV-2 complete vaccine presents a superior alternative to the RNA and DNA vaccines that are delivered through gene therapy vectors and recombinant vaccine products that utilize the entire spike protein, which may elicit off target immune reactions and adverse antibody responses. We are extremely excited to deliver on the promise of our Ii-Key COVID-19 vaccine."

Dr. Jonathan Davis, Chief of Newborn Medicine at Tufts Children's Hospital and a Professor of Pediatrics at Tufts University School of Medicine in Boston who is leading the scientific and clinical advisory board for NuGenerex said, "Once safety is established in adults, it will be important to quickly initiate trials in children and pregnant women. Although children do not become critically ill as frequently as adults, they can still transmit the virus to other children and adults. If we want to fully reopen daycare settings and schools and get parents back to work, immunization of children should be a top priority."

"Pregnant women who develop COVID-19 can also become quite ill, deliver prematurely, and/or transmit the virus to their newborn," added Dr. Davis. "Since studies have shown this Ii-Key peptide technology to be safe and effective in adults with cancer, there is optimism that it will also be well tolerated in these vulnerable populations."

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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