Generex Subsidiary NuGenerex Immuno-Oncology Announces Publication of Positive Results of the AE37 Phase IIb Breast Cancer Trial

Prospective, randomized, single-blinded, multi-center phase II trial of two HER2 peptide vaccines, GP2 and AE37, in breast cancer patients to prevent recurrence

- Conclusion: AE37 Ii-Key peptide vaccine is safe and associated with DFS in sub-sets of breast cancer survivors after 10-year follow-up
- In patients with both advanced stage and HER2 under-expression (HER2 2+, 1+, triple negative) there was a significant improvement in Disease Free Survival (DFS) favoring the vaccine group (AE37 83.0% vs Control 62.5%, p = 0.039, HR 0.375)
- Breast Cancer Research & Treatment; article can be found online: (https://link.springer.com/article/10.1007%2Fs10549-020-05638-x)

MIRAMAR, FL, April 28, 2020 - Generex Biotechnology Corporation (www.generex.com) (OTCQB:GNBT) (http://www.otcmarkets.com/stock/GNBT/quote) is happy to announce that the final results of the Phase IIb clinical trial of AE37 +/- GM-CSF vaccine for the prevention of recurrence of breast cancer have been published in the peer-reviewed journal, Breast Cancer Research & Treatment. In the AE37 arm of this trial, the investigators* found that patients with advanced stage, HER2 under-expression, and TNBC may benefit from AE37 vaccination, and those with both advanced stage and HER2 under expression have a significant clinical benefit to AE37 vaccination, demonstrating earlier DFS plateau that was maintained for up to the ten years of follow-up. The study showed that AE37 induces CD4+ T helper cell stimulation which is required for the effective generation of long-term cell-mediated immunity, and postulates that the AE37 vaccine may have more of an immunoadjuvant effect to augment a vaccine-induced CD8+ T-Lymphocyte (CTL) response. Further, AE37 is able to directly stimulate the HLA-DR alleles with epitopes present in the HER2 protein, increasing interferon gamma (IFN-γ) and CD4+ T-helper (Th1) cells which in turn assist in strong in vivo autologous lysing of tumor cells by CD8+ cells. Thus, the addition of the Ii-Key in AE37 specifically enhances immune responses via the MHC class I pathway. Additionally, the study shows that the Ii-Key acts as an immune system adjuvant, activating both the CD4+ response and the CD8+ response against the HER2 antigenic epitope to which it is attached. The authors point out the benefit of such a complete immune response that combines CD8+ and CD4+ activation may not only induce an immediate cell mediated cytolytic response versus tumor cells but may also induce T-Helper cell mediated long-term immunity to protect against tumor recurrence.

Generex President & CEO Joe Moscato Said, “This is fantastic news for NuGenerex Immuno-Oncology and our AE37 Ii-Key immunotherapeutic peptide vaccine. The study results confirm that patients with advanced stage, HER2 under-expression, and TNBC may benefit from AE37 vaccination, and we now have statistically significant 10-year disease free survival data that demonstrates clinical benefit in the most difficult to treat patients with advanced disease and low HER2 levels, including triple negative breast cancer. For the last three and a half years, we have worked diligently to turn around the NuGenerex Immuno-Oncology development program, and to unlock the true value of the Ii-Key technology. These positive data confirm our ongoing belief in the power of Ii-Key platform to modulate the immune system to fight disease. We will continue to develop AE37 in our ongoing Phase II clinical trial in combination with pembrolizumab (Merck’s Keytruda®) for the treatment of triple negative breast cancer, and we are planning a trial of AE37 in bladder cancer. As we spin out NGIO as a separate public company, we are excited about the opportunities for AE37 and our other Ii-Key immunotherapeutic

peptide vaccines GP100 and TYR for melanoma, and we plan to explore additional tumor associated antigenic epitopes for our Ii-Key immune system modulating platform."

Mr. Moscato continued, "In addition to our efforts to develop Ii-Key peptide vaccines for oncology, the Generex management team is actively involved in a COVID-19 emergency response effort. We are advancing discussions with BARDA and have been working hard to assemble an impressive group of partner organizations to implement an accelerated, multifaceted development program to commercialize our Ii-Key-SARS-CoV-2 peptide vaccine in response to the U.S. government calls for a vaccine solution to the coronavirus crisis. We are working to secure manufacturing, laboratory, clinical, regulatory, and expert medical advisory services with world-class organizations like PPD, Polypeptide Labs, Bachem, Ajinomoto, Thermo-Fisher, CTL Laboratories, and San Diego Center for AIDS Research as well as renowned clinical research sites at Tufts University Medical Center and Wake Forest Baptist Health. Together we have prepared a full proposal for the end-to-end development of an Ii-Key-SARS-CoV-2 vaccine. Additionally, we continue discussions with Canadian health authorities, having held a pre-CTA teleconference last week, and we plan to finalize our regulatory strategy in collaboration with Health Canada in the coming weeks. We will keep our shareholders updated as we progress in our coronavirus vaccine development program using Ii-Key peptides to activate the immune system for protection from COVID-19. And to all of our valued investors, please stay safe and be well."

*Clinical Investigators and Study Managers: Tommy A. Brown II · Elizabeth A. Mittendorf· Diane F. Hale · John W. Myers III · Kaitlin M. Peace ·Doreen O. Jackson · Julia M. Greene · Timothy J. Vreeland · G. Travis Clifton · Alexandros Ardavanis ·Jennifer K. Litton5· Nathan M. Shumway · J. Symanowski · James L. Murray · Sathibalan Ponniah · E. A. Anastasopoulou · N. F. Pistamaltzian · Constantin N. Baxevanis · Sonia A. Perez · Michael Papamichail · George E. Peoples

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, 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.

About EpiVax

EpiVax is a 21-year old privately-held biotechnology company located in Providence, RI, with a broad portfolio of projects including vaccines and immunotherapies for infectious diseases, autoimmunity and cancer. Scientists at EpiVax, led by co-founders Annie De Groot, MD and Bill Martin, lead the field in immunogenicity risk assessment. The ISPRI and iVAX toolkits for therapeutics and vaccines are used by a global roster of companies. Visit www.epivax.com for more information.

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