Generex Biotechnology Announces IND Filing for a Phase II Clinical Trial of AE37 in Combination with Pembrolizumab (Keytruda®) for the Treatment of Triple-Negative Breast Cancer

MIRAMAR, FL, October 29, 2018 / (Business Wire) / -- Generex Biotechnology Corporation (www.generex.com) (OTCQB:GNBT) (http://www.otcmarkets.com/stock/GNBT/quote) today announced that the Company filed an investigational new drug application (IND) with the U.S. Food & Drug Administration (FDA) to initiate *A Phase II Clinical Trial of Pembrolizumab (Keytruda®) in Combination with the AE37 Peptide Vaccine in Patients with Metastatic Triple Negative Breast Cancer*. The trial, sponsored by Generex wholly-owned subsidiary Antigen Express, Inc. (www.antigenexpress.com) and conducted in conjunction with research partners Merck and the NSABP Foundation, Inc. (NSABP), is scheduled to initiate sites in the fourth quarter and to begin enrolling patients in the first quarter of 2019.

Dr. Eric von Hofe, President of Antigen Express, commented, “This is an important milestone in the development of AE37. Combining our promising immunotherapeutic with Merck’s checkpoint inhibitor Keytruda® (pembrolizumab) for the treatment of triple-negative breast cancer represents a novel treatment strategy for a cancer of high unmet need. Previous studies with each agent alone showed promising signs of efficacy. Their complementary mechanisms of action are particularly exciting and point to the importance of the current trial.”

Richard Purcell, Executive Vice President – Research & Development of Generex commented, “This IND filing represents the culmination of a committed effort by the team at Antigen Express and our research partners at the NSABP Foundation. Antigen Express has been a pioneer at the forefront of immuno-oncology for over a decade with our Ii-Key platform that ensures CD4 T-cell activation against any tumor antigen to which the Ii-Key is attached. We are advancing this technology with our lead product AE37 for breast cancer, but also for the treatment of prostate and potentially other cancers that express even low levels of HER2/neu. The Ii-Key platform holds great promise, and we plan to explore collaborations and partnerships in the field of personalized immuno-oncology to maximize value for our investors.”

About AE37

AE37 is an investigational therapeutic cancer vaccine being developed to treat cancer in women with certain types of breast cancer. It is a combination of portions of two proteins that together stimulate the immune system to fight cancer cells.

Up to 80 percent of breast cancers express some level of a protein called HER2. While treatments exist to target HER2 in breast cancer patients with the highest level of HER2 expression (roughly 25%), the majority of patients who have lower levels of expression have more limited treatment options. AE37 consists of a protein derived from the HER2 protein combined with a portion of the MHC class II associated invariant chain which has been termed Ii-Key.

AE37 does not directly target HER2, but instead acts as a vaccine to activate the immune system to recognize the HER2 protein that is expressed on cancer cells as foreign.

AE37 ensures activation of CD4-positive lymphocytes, immune cells that are important in stimulating both the antibody response (antibodies against HER2) and cellular responses directed against the HER2 protein in breast cancer cells. The Ii-Key peptide is coupled with the HER2 protein to ensure a more robust and long-lasting response.

About Generex Biotechnology Corporation

Generex is a strategic, diversified healthcare holdings company with offerings in a variety of services, diagnostics, medical devices, and pharmaceutical development.

The Company's direct-to-patient services support its strategy of all-inclusive access to doctors, diagnostics, therapeutics, and additional health-related services to greatly improve the patient experience in receiving care.

On the provider side, Generex's management services remove administrative burdens in multiple provider settings, including private practice and hospital, allowing doctors to devote more time to patient care.

Revenue from the Company's subsidiaries will support clinical advancement of its wholly owned therapeutic products with a focus in immunotherapeutics based on stimulating critical members of the immune response, known as T helper cells, and its proprietary buccal administration of insulin.

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.

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