Generex Biotechnology Signs Clinical Trial Agreement with the NSABP Foundation, Inc. for Phase II Clinical Trial of AE37 in Combination with Pembrolizumab (Keytruda®) for Treatment of Triple-Negative Breast Cancer

NSABP to Provide Clinical Trial and Site Management Services for
Antigen Express and Research Partner Merck on AE37/Keytruda® Combination Trial

MIRAMAR, FL, November 27, 2018 -- Generex Biotechnology Corporation (OTCMKTS:GNBT) has signed a clinical trial agreement (CTA) with the NSABP Foundation, Inc. (NSABP), to manage a *Phase II* clinical trial of *Pembrolizumab (Keytruda®)* in combination with the AE37 Peptide Vaccine in Patients with Metastatic Triple Negative Breast Cancer.

The clinical trial, sponsored by Generex and conducted in conjunction with Merck, is currently being reviewed by the FDA, and clinical operations including site qualification, drug shipment and packaging, and IRB review and approval are underway, with plans to enroll patients in the first quarter of 2019.

Eric von Hofe, President of Generex's wholly-owned subsidiary Antigen Express, commented, "We are very pleased to be working with the NSABP Foundation on this important trial combining AE37 and Keytruda® in triple-negative breast cancer patients. The extensive expertise of the NSABP Foundation and their network of sites and investigators will be a great asset in this development effort."

Generex EVP of R&D Richard Purcell commented, "This contract with our research partners at the NSABP Foundation provides cost and timeline certainty to our AE37 development program in combination with Keytruda®. We look forward to our continued collaboration with Merck and the NSABP Foundation research team."

Previously, the Company reported that it 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.

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 the NSABP Foundation, Inc.

The NSABP Foundation is a non-profit organization devoted to improving the survival outcome and quality of life of patients with breast or colorectal cancer. The Foundation has a long history of developing new treatments that have improved the standard of care for cancer patients worldwide both through NCI-sponsored studies and in collaboration with industry.

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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