Generex Announces Collaboration with Merck to Evaluate KEYTRUDA® (pembrolizumab) in Combination with AE37 in Patients with Triple-Negative Breast Cancer

July 31, 2017 09:30 AM Eastern Daylight Time MIRAMAR, FL--(BUSINESS WIRE)--Generex Biotechnology Corporation (www.generex.com) (OTCPink:GNBT) today announced that its wholly-owned subsidiary, Antigen Express, Inc. (www.antigenexpress.com) has entered into a clinical trial collaboration agreement with Merck (known as MSD outside the United States and Canada), through a wholly-owned subsidiary, to evaluate Antigen's AE37 cancer vaccine in combination with Merck's anti-PD-1 (programmed death receptor-1) therapy, KEYTRUDA® (pembrolizumab), in patients with metastatic triple-negative breast cancer. The study will evaluate preliminary safety and efficacy of the combination in a Phase II trial.

The combination of AE37 plus KEYTRUDA follows previous studies, in which both therapies have individually shown encouraging results in patients with triple-negative breast cancer. In a controlled, randomized trial of AE37 in 300 breast cancer patients, the most encouraging results were observed in those with triple-negative breast cancer. Similarly, KEYTRUDA has shown encouraging activity in patients with metastatic triple-negative breast cancer. The attractiveness of the combination lies in the different mechanisms of action of the two immunotherapeutic drugs: AE37 specifically activates T cells to attack cancer cells while KEYTRUDA increases the ability of the body's immune system to help detect and fight tumor cells.

"We are excited to be collaborating with Merck, a clear leader in cancer immunotherapy, to advance this important treatment modality in patients with triple negative breast cancer," said Dr. Eric von Hofe, Ph.D., President of Antigen Express. "Both the clinical data as well as mechanistic data on the activity of AE37 and KEYTRUDA in patients strongly argue for the potential benefit of this combination study."

Dr. Samuel Jacobs, MD of the NSABP Foundation, which is collaborating in this study with Antigen Express and Merck, noted that "with single agent immunotherapy in metastatic TNBC the response rate is low, but the benefit in responding patients is strikingly prolonged. We are hoping that with this combination we will see both an increase in the response rate and extended duration of benefit."

CMO and CSO of Generex, Dr. Jason Terrell, added, "This trial unveils our incredibly diverse Ii-key hybrid vaccine platform. AE37 is a hybrid vaccine combining the potent immune-stimulating Ii-key molecule with a breast cancer specific target. Ii-key can similarly be combined with virtually any target to create vaccines across the spectrum of disease processes."

"The agreement with Merck is a pivotal milestone in the advancement of our immunotherapy assets and marks a new phase of Antigen Express clinical development" said Joe Moscato, CEO of Generex. "Given that AE37 alone showed statistically significant efficacy in the triple-negative subpopulation of our prior Phase 2 study," he continued, "we anticipate important new development opportunities when coupled with KEYTRUDA. In particular, this combination study will highlight the unique value of AE37 and pave the way for additional development opportunities in other cancers. We are excited to move this study into the clinic and reinvigorate our immunotherapy work as we approach the end of our company reorganization. This collaboration highlights our commitment to Antigen Express and its assets into the future."

The collaboration agreement is between Antigen Express and Merck. Under the terms of the agreement, the trial will be sponsored by Antigen Express. Additional details were not disclosed.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.

About the NSABP Foundation

The NSABP Foundation is an outgrowth of the National Surgical Adjuvant Breast and Bowel Project, instituted in 1958 as part of the National Cancer Institute's clinical trials program. The founder, Bernard Fisher, MD, was one of the first cancer researchers to realize the value of the randomized clinical trial in answering questions about the development, progression, and treatment of this disease. From the time of the NSABP's first studies, the randomized trial has been its primary research tool, and over the years has established record of designing and conducting clinical trials that have changed the way breast cancer is treated and prevented.

In its history the NSABP has enrolled more than 110,000 women and men in clinical trials in breast and colorectal cancer. It has research sites at nearly 700 major medical centers, university hospitals, large oncology practice groups, and health maintenance organizations in the United States, Canada, and Ireland. At those sites and their satellites, about 5000 physicians, nurses, and other medical professionals conduct NSABP treatment and prevention trials.

About Generex Biotechnology Corporation

Generex is engaged in the research, development, and commercialization of drug delivery systems and technologies. Generex has developed a proprietary platform technology for the delivery of drugs into the human body through the oral cavity (with no deposit in the lungs). The Company's proprietary liquid formulations allow drugs typically administered by injection to be absorbed into the body by the lining of the inner mouth using the Company's proprietary RapidMist™ device. Antigen Express, Inc.

is a wholly owned subsidiary of Generex. The core platform technologies of Antigen Express comprise immunotherapeutic vaccines for the treatment of malignant, infectious, allergic, and autoimmune diseases. Antigen Express has pioneered the use of specific CD4+ T-helper stimulation technologies in immunotherapy. One focuses on modification of peptides with Ii-Key to increase potency, while a second relies on inhibition of expression of the Ii protein. Antigen Express scientists, and others, have shown clearly that suppression of expression of the Ii protein in cancer cells allows for potent stimulation of T-helper cells and prevents the further growth of cancer cells. For more information, visit the Generex website at www.generex.com or the Antigen Express website at www.antigenexpress.com.

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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