

Generex Provides Summary of li-Key Hybrid Vaccine Platform

*Follow-Up to Antigen Express – Merck
AE37 - KEYTRUDA® Collaboration*

August 7, 2017 09:30 AM Eastern Daylight Time MIRAMAR, FL--(BUSINESS WIRE)--Generex Biotechnology Corporation (www.generex.com) (OTCPink:GNBT) today provided the following summary of the li-Key Hybrid Vaccine Platform under development by its wholly-owned subsidiary, Antigen Express, Inc. (www.antigenexpress.com). This summary has been prepared by Dr. Jason B. Terrell, MD, the Company's Chief Medical and Scientific Officer, as a follow-up to last week's announcement by Generex of a clinical trial collaboration agreement between Antigen Express and 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.

Summary

Immunotherapy requires the generation of a robust and specific immune response to target antigens. Inadequate immune activation results in subclinical efficacy. Nonspecific immune activation results in side effects and toxicity. li-Key hybrid vaccines greatly enhance immune activation specific to the therapeutic target antigen.

A principle mechanism of immunotherapy involves "foreign" or "disease specific" antigens being presented on MHC Class II molecules to CD4+ T Cells. The MHC Class II molecule is present on Antigen Presenting Cells. The CD4 molecule of T Cells interacts with the MHC Class II molecule to recognize the antigen being presented. This triggers a cascade of immunologic responses directed at recognizing and killing diseased cells bearing the target antigen. These target antigens can be cancer specific, infectious disease specific, or specific to any condition or disease process.

li-Key is a four amino acid peptide that is synthetically linked to specific target antigen epitopes. The li-Key peptide binds allosterically to a region adjacent to the MHC Class II antigen binding domain. This molecular interaction displaces existing resident antigens while anchoring the linked target antigen securely within the antigen binding domain, allowing the li-Key hybrid to bypass all requirements for antigen processing and directly "hijack" MHC Class II molecules. This greatly enhances activation of CD4+ T Cells resulting in both direct cell-specific cytotoxic immune responses and improved long-term immunologic memory - up to 250 times greater potency than native antigens in-vitro (Sotiriadou 2007). Preclinical and/or Phase I data currently supports the use of li-

Key hybrid vaccines in breast cancer, prostate cancer, cervical cancer, melanoma, HIV, swine flu, and diabetes.

In July 2017 GenereX Biotechnology announced a Phase II trial with a subsidiary of Merck (known as MSD outside the United States and Canada), combining the Antigen Express AE37 hybrid vaccine with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in collaboration with the NSABP Foundation (www.nsabp.org) for patients with advanced triple-negative breast cancer. This trial will validate expansion of the li-Key platform to a host of therapeutic indications. In the field of oncology alone, the vast potential of li-Key hybrid vaccines can be illustrated by the 2009 article, "The Prioritization of Cancer Antigens: A National Cancer Institute Pilot Project for the Acceleration of Translational Research." This article outlines over 50 potential cancer target antigens, each of which represents a new li-Key hybrid immunotherapeutic vaccine.

Thus far this summary has focused on activation of the Type I Helper T Cell immunologic response to induce recognition and killing of diseased cells bearing the target antigen. On the other end of the immune spectrum, li-Key hybrid vaccines can be administered to selectively activate the Type II Helper T Cell immunologic response to induce immune tolerance to harmful target antigens, such as those implicated in autoimmune disease, allergy, and transplant rejection.

In conclusion, the li-Key hybrid vaccine platform offers incredible diversity, able to selectively "turn on" or "turn off" the immune response depending on the disease process.

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

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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.

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