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Generex receives IND approval from FDA

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Generex Biotechnology Corporation has announced that the FDA had reviewed the company's investigational new drug (IND) application and given notification that the study can proceed. The study: A Phase II Clinical Trial of Pembrolizumab (Keytruda) in Combination with the AE37 Peptide Vaccine in Patients with Metastatic Triple Negative Breast Cancer, is sponsored by Generex and conducted under a collaboration agreement with Merck and a clinical trial agreement with the NSABP Foundation, Inc. (NSABP).

The combination study builds on previous clinical studies of both AE37 and Keytruda. AE37, a cancer vaccine, was the subject of a 300 patient prospective, randomized and single-blinded Phase II study in patients with breast cancer. That study showed a strong trend toward reduced relapses,particularly in patients with triple negative breast cancer. Keytruda also has shown encouraging results in patients with triple negative breast cancer when used as monotherapy. The complementary mechanisms of action of the two drugs suggest the combination may have the potential to be better than either alone.

AE37 is unique among therapeutic cancer vaccines in that it ensures specific activation of CD4+ T helper cells, which are critical in generating an effective immune response. Its improved immunological potency, along with an excellent safety profile, offers particular advantages for combination studies. In addition to the Phase II study in breast cancer patients, AE37 also has been tested in a Phase I study in prostate cancer patients. AE37 treated patients have consistently displayed a robust, long-lasting and specific response to the vaccine.

Liesha Emens, M.D., Ph.D., Principal Investigator for the study and Professor of Medicine at the University of Pittsburgh Medical Center commented: "So far, metastatic triple negative breast cancer patients treated upfront with immunotherapy benefit clinically from immune checkpoint immunotherapy only if their tumors contain PDL1+ cells. Increasing the number of patients with immune-activated tumors should bring the benefit of immunotherapy to even more patients. This Phase II trial will test whether the AE37 vaccine may trigger immunity in triple negative breast cancer patients, priming them for clinical benefit from immune checkpoint blockade."

Eric von Hofe, President of NuGenerex-ImmunoOncology commented: "We are gratified to see this important trial moving forward. While we have tested AE37 in breast and prostate cancer patients, there is good rationale for inclusion of AE37 in the treatment regimen of a variety of additional cancer types of high unmet need. Gastric, colon, ovarian and bladder cancers all express the same tumor target expressed in breast and prostate cancer that AE37 activates the immune system to recognize."

About AE37

AE37 is an investigational therapeutic cancer vaccine being developed to treat 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 rather acts as a vaccine to activate the immune system to recognize the HER2 protein, which 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.