Tolerx Completes Enrollment in DEFEND-1, A Phase 3 Type 1 Diabetes Study With Otelixizumab

CAMBRIDGE, Mass., Jan. 7 /PRNewswire/ -- Tolerx, Inc., today announced the completion of patient enrollment in its Phase 3 clinical study DEFEND-1, which is evaluating the safety and efficacy of otelixizumab, a targeted T cell immunomodulator, in patients with new-onset autoimmune type 1 diabetes.

The DEFEND-1 (**D**urable Response Therapy **E**valuation **F**or **E**arly or **N**ew-Onset Type 1 **D**iabetes) study enrolled 240 patients, aged 12-45 years with newly diagnosed autoimmune type 1 diabetes. The DEFEND-1 study is investigating the ability of otelixizumab to preserve beta cell function, which may reduce the risk of both short- and long-term complications of the disease. Patients will be monitored during the 12-month follow-up period and c-peptide levels (a surrogate measure of beta cell function) will be measured as the primary endpoint. Secondary endpoints will evaluate the patient's ability to maintain excellent glycemic control as measured by HbA1c levels and the amount of daily injected insulin required.

Dr. Paolo Pozzilli, Professor of Endocrinology & Metabolic Diseases at the University Campus Bio-Medico in Rome, Italy, and a DEFEND-1 investigator commented: "Reaching full enrollment in DEFEND-1 is a major accomplishment for the type 1 diabetes community and furthers the development of innovative immunomodulating therapies for our patients. We will continue to work with Tolerx to further otelixizumab's clinical development and to validate its promise of beta cell preservation in new-onset autoimmune type 1 diabetes patients."

Peter A. Gottlieb, MD, Associate Professor of Pediatrics and Medicine at the Barbara Davis Center at the University of Colorado at Denver, known for his involvement in many types of clinical trials for the prevention and treatment of diabetes, noted that, "The continuous otelixizumab dose regimen optimization efforts have been a major translational research focus. These important research efforts are enabling us, in the DEFEND development program, to evaluate the potential ability of otelixizumab to provide a long-term immunologic remission after a short course of therapy. If successful in the clinic, this would be a significant step forward."

Tolerx also announced today its intention to conduct a second confirmatory Phase 3 study of otelixizumab in new-onset autoimmune type 1 diabetes. Further details of the design and timing of the study, to be named DEFEND-2, will be forthcoming.

"The on-time completion of patient enrollment in DEFEND-1 represents a major milestone for Tolerx," said Dr. Douglas J. Ringler, President and Chief Executive Officer of Tolerx. "We are very grateful for the dedication of the patients, their caregivers and our clinical trial investigators for making it possible to reach our enrollment target. As part of our clinical development program to reach regulatory approval for otelixizumab, we will now quickly transition to the launch of DEFEND-2, a confirmatory study, to maintain enrollment momentum and enthusiasm generated to date in the type 1 diabetes community."

About the DEFEND-1 Study

DEFEND-1 is a randomized, placebo-controlled Phase 3 study that has achieved its target enrollment of 240 patients, age 12 to 45, with newly diagnosed autoimmune type 1 diabetes. DEFEND is being conducted at over 100 study centers throughout Europe and North America. The study is designed to evaluate whether a single course of otelixizumab, administered not more than 90 days after the initial diagnosis of autoimmune type 1 diabetes, will preserve beta cell function as measured by c-peptide, a surrogate measure of beta cell function. The primary endpoint is measurement of c-peptide. For more information about DEFEND, please visit www.DefendAgainstDiabetes.com.

About Type 1 Diabetes

Diabetes (medically known as diabetes mellitus) is the name given to disorders in which the body has difficulty regulating its blood glucose (sugar) level. There are two major types of diabetes: type 1 and type 2. Type 1, previously known as juvenile diabetes or insulin-dependent diabetes, is a disorder of the body's immune system. In type 1 diabetes, the immune system attacks and destroys the insulin-producing beta cells in the pancreas. As a result of the decrease in endogenous (natural) insulin production, patients must monitor their glucose levels frequently and administer insulin regularly to control their blood glucose levels.

About Otelixizumab

Otelixizumab is a targeted T cell immunomodulator being developed for the treatment of type 1 diabetes and other autoimmune diseases. Otelixizumab targets CD3, a T lymphocyte receptor involved in normal cell signaling.

Otelixizumab has not yet been approved for marketing. Data suggest that the antibody may work in patients with type 1 diabetes who have residual beta cells by blocking the function of effector T cells that mistakenly attack and destroy insulin-producing beta cells, while stimulating regulatory T cells that are understood to protect against effector T cell damage, thus preserving the beta cells' ability to make insulin.

About Tolerx

Tolerx, Inc., a world leader in the understanding of T cell function, is developing novel therapies intended to treat autoimmune diseases, diabetes, and cancer by specifically modulating T-cell activity. The company's pipeline includes its lead candidate, otelixizumab, a targeted T-cell immunomodulator partnered with GlaxoSmithKline in Phase 3 development for the treatment of type 1 diabetes; a Phase 1 candidate, MTRX1011A, an anti-CD4 antibody that is being developed in collaboration with Genentech, Inc. for the treatment of autoimmune indications; and two pre-clinical candidates, TRX518 and TRX385, that enhance immune responses and are being evaluated for potential benefit in the treatment of cancer, chronic viral diseases, and as vaccine adjuvants. Tolerx is a privately held company headquartered in Cambridge, MA USA. For more information, please visit **www.tolerx.com**.

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