

Tolerx Announces Amendment to Phase 3 DEFEND Protocol

Amendment Expands Treatment Population and Allows For More Convenient Dosing Regimen

CAMBRIDGE, MA - August 11, 2009- Tolerx, Inc., a biopharmaceutical company engaged in the discovery and development of novel therapies for immune-mediated diseases, today announced changes to the protocol for its Phase 3 clinical trial DEFEND, which is testing the safety and efficacy of otelixizumab, a targeted T cell immunomodulator, in patients with new-onset autoimmune type 1 diabetes.

The DEFEND (Durable Response Therapy Evaluation For Early or New-Onset Type 1 Diabetes) protocol amendment includes two key changes to the study: expansion of the eligible patient age range from 18-35 years to 12-45 years, and the shortening of the infusion time for each administration of otelixizumab from 2 hours to 30 minutes. Both of these enhancements are supported by clinical data derived from Tolerx's ongoing Phase 2 study called TTEDD.

"From a clinical perspective, I believe this amendment significantly improves the protocol for the DEFEND trial," said Peter A. Gottlieb, MD, Associate Professor of Pediatrics and Medicine at the Barbara Davis Center at the University of Colorado at Denver, and a principal investigator in the DEFEND study. "Most notably, through the expansion of the patient age range to include adolescents, Tolerx is widening the options available to physicians interested in providing new investigational treatment options to this important and growing adolescent patient population."

Dr. Douglas J. Ringler, President and Chief Executive Officer of Tolerx, also commented on the news: "We are pleased with this amendment on multiple levels and are hopeful that both the expansion of the target population and the more convenient dosing regimen will further expand the enthusiasm for this trial in the diabetes community. Our commitment to type 1 diabetes patients is evidenced in our efforts to develop a short, convenient course of otelixizumab therapy, which may provide a potential for preserving beta cells and possibly improving disease control."

It is estimated that, in the United States, approximately 36,000 patients are diagnosed each year with autoimmune type 1 diabetes. Of those newly diagnosed, approximately 35% are adolescent patients between the ages of 12 and 17 years who are now eligible for enrollment in the DEFEND trial.

About the DEFEND Study

DEFEND is a randomized, placebo-controlled Phase 3 trial intended to enroll approximately 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 trial 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 will be a measurement of C-peptide. For 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 is a biopharmaceutical company engaged in the discovery and development of novel therapies for immune-mediated diseases. 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.