# Tolerx and GlaxoSmithKline Announce Phase 3 Defend-1 Study of Otelixizumab in Type 1 Diabetes Did Not Meet Its Primary Endpoint

Bio-Medicine.Org

CAMBRIDGE, Mass. and LONDON, March 11, 2011 /PRNewswire/ -- Tolerx, Inc. and GlaxoSmithKline (GSK) today announced that the Phase 3 DEFEND-1 study of otelixizumab, an investigational humanized anti-CD3 monoclonal antibody, did not meet the primary efficacy endpoint of change in C-peptide at month 12 in patients with new-onset autoimmune type 1 diabetes.

Following preliminary review of the data, no new or unexpected treatment-related safety concerns have emerged during the DEFEND-1 study. Study investigators and regulatory agencies have been notified of the DEFEND-1 study outcome.

GSK will continue to explore additional dosing regimens to inform decisions about the future clinical development programme for otelixizumab. New recruitment and dosing in the DEFEND-2 study, the ongoing confirmatory Phase 3 study with a design similar to DEFEND-1, has been suspended pending review of the DEFEND-1 results.

"While we are disappointed in the DEFEND-1 results of otelixizumab, we remain committed to the development and commercialization of the candidates in our pipeline, each of which has a distinct mechanism and target for correcting abnormal immune responses," said Douglas J. Ringler, VMD, President and Chief Executive Officer of Tolerx. "Our immunotherapy candidates represent some of the latest scientific advances in harnessing the immune system for therapeutic benefit, including TRX518 which is a showpiece of our pipeline as an immunotherapy to treat cancer."

"Clearly these are disappointing data, but we are committed to working with Tolerx to better understand the results of this study and determine the way forward," said Jackie Parkin, Medicines Development Leader, GlaxoSmithKline.

**Tolerx Pipeline**

In addition to otelixizumab, Tolerx has four product candidates in various stages of development, and each candidate is based on Tolerx's immunology expertise in understanding how therapies can be designed
'/>"/>

SOURCE [1]

**Source URL (retrieved on *04/18/2015 - 12:37am*):**
http://www.mdtmag.com/news/2011/03/tolerx-and-glaxosmithkline-announce-phase-3-defend-1-study-otelixizumab-type-1-diabetes-did-not-meet-its-primary-endpoint

**Links:**
[1] http://www.bio-medicine.org/medicine-technology-1/Tolerx-and-GlaxoSmithKline-Announce-Phase-3-Defend-1-Study-of-Otelixizumab-in-Type-1-Diabetes-Did-Not-Meet-Its-Primary-Endpoint-15419-1/