The Lancet Publishes Data from Protege, MacroGenics' Phase 3 Clinical Study of Teplizumab in Type 1 Diabetes Patients

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ROCKVILLE, Md., June 28, 2011 /PRNewswire/ -- MacroGenics, Inc., a privately held biotechnology company that develops immunotherapeutics to treat autoimmune disorders, cancer and infectious diseases, announced the publication in *The Lancet* of results from Protege, a Phase 3 clinical study of teplizumab in type 1 diabetes. Exploratory, post-hoc analyses suggest that teplizumab, an anti-CD3 monoclonal antibody, when used in a 14-day full dose regimen, preserves C-peptide and increases the percentage of patients requiring very low doses of insulin (< 0.25 U/kg/day) with good glycemic control (glycosylated hemoglobin, or HbA1C < 7%) compared to placebo. In addition, these analyses revealed that certain subpopulations may be more likely to respond to teplizumab treatment. These findings also were presented today by Dr. Nicole Sherry (Massachusetts General Hospital for Children) at the annual American Diabetes Association meeting.

Protege is a two-year, randomized, double-blind, placebo-controlled clinical trial, with 513 patients aged 8–35, recently diagnosed with type 1 diabetes, who were enrolled and treated at 83 clinical centers in North America, Europe, Israel, and India. Participants were allocated 2:1:1:1 to receive daily infusions of teplizumab (full dose for 14 days, 1/3 dose for 14 days, or full dose for 6 days) or placebo at baseline and at 6 months. The primary composite endpoint of the Protege study was the percentage of patients with insulin use < 0.5 U/kg/day and HbA1C < 6.5% at 1 year. Although teplizumab was shown to have an acceptable safety profile, the primary endpoint was not achieved, as had been previously announced in a joint communication with Eli Lilly and Company in October 2010. Protege is ongoing and will complete the 2-year follow-up in 2011.

The peer-reviewed article appearing in *The Lancet* is titled, "Teplizumab for treatment of type 1 diabetes (Protege study):
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