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

ROCKVILLE, MD., June 28 /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 Protégé, 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.

Protégé 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 Protégé 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. Protégé 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 (Protégé study): 1-year results from a randomized, placebo-controlled trial," by Sherry, et al.[1] and provides the results of per protocol as well as exploratory, post hoc analyses. The findings suggest that "future studies of immunotherapeutic intervention with teplizumab might have increased success in prevention of a decline in beta-cell function (measured by C-peptide) and provision of glycaemic control at reduced doses of insulin if they target patients early after diagnosis of diabetes and children."

The article indicates that teplizumab treatment may preserve beta cell function as measured by C-peptide, allowing less insulin use to achieve the same glycemic control as patients receiving placebo. A greater proportion of patients in the teplizumab groups were able to discontinue or use very low doses of insulin compared to the placebo group. A reduced insulin requirement while maintaining glycemic control appears to support teplizumab having a biological effect.

In the safety analyses, the proportion of patients who had adverse events and serious adverse events was similar across the four study groups. Rash was the most common clinical adverse event reported more frequently with teplizumab than placebo. Mild cytokine release syndrome was infrequent but greater in treatment groups compared to placebo. The safety profile was characterized by transient increases in some liver function test results and transient decreases in white cells that prevent infections. However, no increase in overall infections was seen.

"We are very pleased to have teplizumab Phase 3 data published in this prestigious journal," stated Dr. Scott Koenig, President and CEO of MacroGenics. "Although the Protégé study missed its primary endpoint, the data appear to indicate that teplizumab has a desired biological effect in certain subpopulations with a potentially meaningful therapeutic benefit for patients with recent-onset type 1 diabetes. These groups include patients for whom treatment is begun = 6 weeks after diagnosis and in children 8 -11 years old. In the coming months, MacroGenics will be exploring possible pathways forward for continued development of teplizumab."

About Type 1 Diabetes

Type 1 diabetes is an autoimmune disease in which the body's immune system attacks and destroys the insulin-producing beta cells of the pancreas. Insulin is a hormone that is needed to convert sugar (glucose), starches and other food into energy needed for daily life. People with type 1 diabetes must take multiple injections of insulin daily or continually infuse insulin through a pump to manage their blood glucose levels.

Type 1 diabetes, previously known as juvenile diabetes, usually strikes in childhood, adolescence, or young adulthood, but lasts for a lifetime. Of the nearly 24 million Americans who have diabetes, as many as 3 million may have type 1.

About Teplizumab

Teplizumab, also called MGA031 and hOKT3-gamma1 (Ala-Ala), is a humanized, anti-CD3 monoclonal antibody. Teplizumab binds to an epitope of the CD3-epsilon chain expressed on mature T lymphocytes and, by doing so, may modulate the pathological immunologic responses underlying multiple autoimmune diseases. Specifically, teplizumab may inhibit unwanted effector T cells and enhance beneficial regulatory T cell functions, thus promoting immune tolerance. MacroGenics retains full worldwide rights to teplizumab.

About MacroGenics, Inc.

MacroGenics is a private, venture-backed biotechnology company that focuses on the discovery, development and delivery to patients of novel biologics for autoimmune disorders, cancer and infectious diseases. The company has built a fully-integrated set of capabilities in antibody-based product development which supports its innovative pipeline of clinical stage product candidates. MacroGenics' proprietary research is based on three core technology platforms, which include: (1) a method for generating cancer stem-like cells; (2) Dual-Affinity Re-Targeting (or DART) technology, which allows the company to incorporate multiple specificities within a single recombinant molecule; and (3) Fc optimization, which enhances antibody-dependent effector functions. The company has global product development collaborations with Boehringer Ingelheim and Pfizer Inc. For more information about MacroGenics, please visit www.macrogenics.com.

Statements made in this news release that are not historical facts are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "expects," "believes," "intends," and similar expressions are intended to identify forward-looking statements. Actual results may differ materially from those projected in any forward-looking statement. Specifically, there are a number of important factors that could cause actual results to differ materially from those anticipated, such as the Company's ability to raise additional capital, and risks related to the Company's ability to initiate, and enroll patients in, planned clinical trials. You should not place undue reliance on any forward-looking statements. The Company assumes no obligation to update any forward-looking statements as a result of new information, future events or developments, except as required by law.

Contacts:
Scott Koenig, M.D., Ph.D., President and CEO
or Jim Karrels, Vice President, CFO
both of MacroGenics, Inc., +1-301-251-5172, info@macrogenics.com

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[1] Sherry N, Hagopian W, Ludvigsson J, et al. Teplizumab for treatment of type 1 diabetes (Protégé study): 1-year results from a randomized, placebo-controlled trial. www.thelancet.com. Published online June 28, 2011; DOI:10.1016/S0140-6736(11) 60931-8.