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# MacroGenics Receives Orphan Drug Designation from FDA for Monoclonal Antibody to Treat Type 1 Diabetes

## Pivotal Trial of CD3 Monoclonal Antibody to Begin in 2006

**Rockville, MD. October 10, 2006.** MacroGenics, Inc. announced today that its lead product candidate, MGA031, a humanized, Fc-engineered anti-CD3 monoclonal antibody, has received orphan drug designation from the Food and Drug Administration (FDA) for treatment of recent-onset type 1 diabetes mellitus (T1DM). MacroGenics anticipates initiating a Phase 2/3 trial to study MGA031 in patients with recent-onset T1DM in the fourth quarter of 2006. MGA031 is the designation for hOKT3-gamma-1 (Ala-Ala) manufactured by MacroGenics.

In previous clinical trials, this anti-CD3 monoclonal antibody was shown to interfere with the autoimmune mechanism underlying type 1 diabetes, potentially slowing its progression, and therefore improving the health and quality of life of patients with diabetes, said Scott Koenig, M.D., Ph.D., President and Chief Executive Officer, MacroGenics. In a short period of time, we completed GMP manufacturing and made significant progress in advancing MGA031 toward registration trials. We believe that MGA031 represents a novel mechanism of action that has the potential to change the treatment paradigm for type 1 diabetes. We also believe that MGA031 may have applicability in other autoimmune diseases, including psoriatic arthritis and multiple sclerosis.

Orphan drug designation is a special status given to products for rare diseases or conditions upon request of a sponsor and approval from the FDA. Orphan drug designation qualifies MacroGenics for exclusive marketing rights in the United States for seven years if the company is first to receive marketing approval for an anti-CD3 monoclonal antibody of the same sequence for the indication. The designation also positions MacroGenics to benefit from certain tax credits and waives the companys obligation to pay FDA application user fees for this product as required by the Prescription Drug User Fee Act (PDUFA).

About MGA031

CD3 is a key signaling cluster of molecules within the T cell receptor complex. MGA031 [hOKT3-gamma-1 (Ala-Ala)] is a humanized monoclonal antibody that binds to an epitope of the CD3-epsilon chain expressed on mature T cells. It is capable of interfering with the autoimmune mechanisms that lead to the destruction of the pancreatic islet cells in patients with T1DM and has potential applications in other autoimmune and inflammatory diseases.

In a June 2005 *Diabetes* publication, Dr. Kevan Herold, now at Yale University and a consultant to MacroGenics, reported two-year follow-up data regarding 21 patients who received a single course of hOKT3-gamma-1 (Ala-Ala) within six weeks of their diagnosis of type 1 diabetes. The patients who received hOKT3-gamma-1 (Ala-Ala) had improved C-peptide responses following a mixed meal tolerance test, reduced hemoglobin $A_{1c}$ ($HbA_{1c}$) levels, and lower insulin requirements for at least 2 years following the initial treatment compared to the control population. C-peptide responses measure a patients residual beta cell function and ability to produce insulin. $HbA_{1c}$ is a measure of metabolic control that reflects the amount of glucose in a patients blood over a 3-month timeframe.

About Type 1 Diabetes Mellitus

The American Diabetes Association reports that approximately one in every 400 to 500 children and adolescents will develop T1DM, also known as juvenile diabetes. T1DM usually has its onset in subjects under the age of 30 and more than one-half of the cases develop in individuals under the age of 18. T1DM is caused by a T-lymphocyte-dependent autoimmune attack on the pancreatic beta cells that ultimately destroys the capacity of the beta cells to produce amounts of insulin adequate to control excessive blood glucose levels. Unless the destruction of the pancreatic islet cells is halted early in the course of the disease, irreversible morbidities always develop.

In the absence of a cure, all subjects with T1DM require life-long, intensive insulin replacement therapy. Diabetic subjects are prone to a variety of complications from the disease, including heart and kidney disease, high blood pressure and blindness. Accordingly, a treatment that aims to slow the progression of disease has the potential to substantially improve the health and quality of life of these subjects.

About MacroGenics, Inc.

Founded in 2000, MacroGenics is a private, venture-backed biotechnology company headquartered in Rockville, Maryland that focuses on the development, manufacture, and commercialization of immunotherapeutics for autoimmune disorders, cancer, and infectious diseases. The companys proprietary Fc engineering technology offers ways of improving antibody function, such as enhancing its ability to eliminate cancer cells, cells that contribute to autoimmune disorders, or those infected with certain pathogens. The company is developing first-in-class product candidates from its autoimmunity, oncology and infectious disease portfolios.

*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 Companys ability to raise additional capital, and risks related to the Companys 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.*