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MacroGenics Announces the Initiation of a Phase 2 Clinical Trial to Evaluate the Safety and Efficacy of Monoclonal Antibody MGAWN1 in Subjects with Suspected Central Nervous System Infection Due to West Nile Virus

ROCKVILLE, Md., July 13, 2009 /PRNewswire/ -- MacroGenics, Inc. today announced the initiation of the PARADIGM trial, a Phase 2 clinical study evaluating MGAWN1, a humanized monoclonal antibody, for the treatment of individuals with suspected central nervous system infection due to West Nile Virus (WNV). MacroGenics, a privately held biotechnology company that develops immunotherapeutics to treat autoimmune disorders, cancer and infectious diseases, was awarded a $50 million contract in September 2006 from the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, to support the development of MGAWN1.

The PARADIGM trial is a randomized, double-blind, multicenter, placebo-controlled study that is designed to evaluate the safety and efficacy of MGAWN1 in patients > 18 years of age with signs and symptoms of acute West Nile Neuroinvasive Disease. Approximately 20 sites in North America will be utilized for the conduct of the PARADIGM trial. For more information on the PARADIGM trial, please see www.clinicaltrials.gov.

MacroGenics also announced today the completion of a Phase 1 study of MGAWN1 in healthy volunteers, with the last patient having completed treatment in late 2008. This randomized, double-blind, dose-escalation cohort study was designed to evaluate the safety, tolerability, and pharmacokinetics of a single infusion of MGAWN1 in healthy adults. The study demonstrated the drug to be safe and well tolerated at all doses tested.

"We are delighted with the initiation of the PARADIGM trial as well as the completion of the Phase 1 trial," stated Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "Currently, there are no approved treatments for individuals with severe West Nile Virus infection. These patients are hospitalized and receive supportive care. Therefore, a therapy that neutralizes the virus and could possibly reduce or prevent complications associated with West Nile Neuroinvasive Disease would represent a significant advancement for these patients."

About MGAWN1

MGAWN1 is a humanized monoclonal antibody that specifically recognizes the envelope (E) protein of WNV. MGAWN1 exhibits potent neutralizing and fusion-inhibitory activity against WNV in laboratory studies conducted in vitro and in vivo. MGAWN1 has a specific activity that is orders of magnitude higher than that of an intravenous immune globulin (IVIG) product when tested in laboratory studies.

About West Nile Virus

West Nile Virus has widespread prevalence throughout the U.S. (http://www.cdc.gov/ncidod/dvbid/westnile/Mapsactivity/surv&control08Maps.htm) and other parts of North America. Approximately 20% of humans infected with WNV experience West Nile Fever with clinical symptoms that include fever, headache, body aches, skin rash and swollen lymph glands. In approximately 1% of human infections, WNV enters the brain and causes severe, life-threatening neuroinvasive disease in the form of encephalitis, meningitis or acute flaccid paralysis. West Nile Neuroinvasive Disease (WNND) is associated with significant morbidity, and long-term neurological effects are common among survivors.

Since 1999, there have been more than 28,000 cases of confirmed symptomatic WNV infection in the U.S., which include more than 11,000 WNND cases and more than 1,100 deaths. In 2008, 1,356 cases of WNV infection were reported to the Centers for Disease Control and Prevention (CDC) for the year with 44 of these cases resulting in death. WNV is now the most common cause of epidemic viral encephalitis in the U.S., and it will likely remain an important cause of neurological disease for the foreseeable future. Since 2002, more than 4,500 cases of clinical WNV infection have been reported in Canada. No effective therapy or vaccine is available for humans. For more information about WNV, including maps of WNV activity, please visit www.cdc.gov/WestNile.

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. Since its founding in 2000, the company has built a fully-integrated set of capabilities in monoclonal antibody product development. The company's product development efforts leverage three proprietary technology platforms: (1) cancer stem-like cells; (2) Dual Affinity Re-Targeting (DART), which allows the company to incorporate multiple specificities within a single molecule; and (3) Fc optimization, which enhances antibody-dependent effector functions. These powerful sets of capabilities and technology platforms have enabled MacroGenics to build a proprietary pipeline of innovative product candidates. The company's lead program, teplizumab, is an anti-CD3 antibody being developed for the treatment of autoimmune diseases. In October 2007, MacroGenics and Eli Lilly announced a global strategic alliance to develop and commercialize teplizumab as well as other potential next-generation anti-CD3 molecules. 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