MacroGenics to Receive $10 Million Milestone Payment from Servier for Dosing the First Patient in a Phase 1 Dose Expansion Trial of MGA271

Study to examine safety, pharmacokinetics and anti-tumor effect of potential first-in-class B7-H3 targeted cancer immunotherapy

ROCKVILLE, Maryland, August 20, 2013—MacroGenics, Inc., a clinical-stage biopharmaceutical company focused on discovering and developing innovative monoclonal antibody-based therapeutics for the treatment of cancer and autoimmune diseases, announced that the first patient has been dosed in a Phase 1 dose expansion cohort trial of MGA271. MGA271 is an Fc-optimized monoclonal antibody that targets B7-H3, which is over-expressed on a wide variety of solid tumor types and is a member of the B7 family of molecules that are involved in immune regulation. This milestone triggers a $10 million payment to MacroGenics from its partner, Les Laboratoires Servier, or Servier.

The dose expansion portion of this Phase 1 clinical trial of MGA271 is designed to further evaluate safety and pharmacokinetics at a weekly dose of 15 mg/kg. The dose expansion portion of the trial also includes an early evaluation of the potential anti-tumor activity of MGA271. MacroGenics plans to enroll 45 patients within three cohort groups: two with specific tumor types of 15 patients each, and a third cohort composed of other B7-H3-expressing tumor types. MacroGenics is enrolling patients in the United States and expects to complete the Phase 1 trial in 2014. Servier has indicated that it intends to evaluate MGA271 in 45 additional cancer patients representing additional tumor types beginning in the fourth quarter of 2013.

“MGA271 has significant potential to treat a variety of solid tumors and we are very pleased to reach this milestone in the product candidate’s ongoing development,” said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. “We intend to assess and prioritize future indications for MGA271 clinical trials based on data from these dose expansion cohorts and determine the best path forward to potential approval and commercialization.”

In the dose escalation portion of the Phase 1 clinical trial, 26 patients were enrolled, representing 15 different types of tumors. Ten patients received additional cycles of MGA271 treatment and all have had stable disease at the first tumor re-assessment. The most frequent adverse events in the trial were mild or moderate infusion reactions. No dose-limiting toxicity was observed.

“Servier is very pleased to take this additional step in the development of MGA271,” stated Stéphane Depil, M.D., Ph.D., who leads Oncology Research & Development at Servier. “We are encouraged by the initial potential for MGA271 in the treatment of a variety of B7-H3-expressing solid tumors.”

"Servier is committed to developing first-in-class, innovative drugs in oncology, such as MGA271, which may ultimately deliver an innovative treatment for cancer patients," said Dr. Emmanuel Canet, President of Research and Development at Servier. "The various product candidates included in our two alliances with MacroGenics, including MGA271 and three oncology DART™ programs, are advancing as we had hoped."

Background on MGA271

MGA271 is a humanized, Fc-optimized monoclonal antibody that targets B7-H3, a member of the B7 family of molecules which are involved in immune regulation, and is over-expressed on a wide variety of solid tumor types. B7-H3 is over-expressed on differentiated tumor cells and cancer stem-like cells as well as on the supporting tumor vasculature and underlying tissues. MGA271 is designed to destroy all of these components of the cancer in addition to reducing its inhibitory properties on T cells.

Servier MGA271 Collaboration

In November 2011, MacroGenics entered into a collaboration agreement with Servier. Under this collaboration, MacroGenics granted Servier an option to obtain an exclusive license to develop and commercialize MGA271 in all countries other than the United States, Canada, Mexico, Japan, South Korea and India. MacroGenics received a $20 million option grant fee up-front, will receive a $10 million milestone payment in the third quarter of 2013 in connection with the enrollment of the first patient in the Phase 1 dose expansion trial and may be eligible to receive up to an additional approximately $410 million in license grant fees, and clinical, development, regulatory and sales milestone payments.

About MacroGenics, Inc.

MacroGenics is a clinical-stage biopharmaceutical company focused on discovering and developing innovative monoclonal antibody-based therapeutics for the treatment of cancer and autoimmune diseases. The company generates its pipeline of product candidates from its proprietary suite of next-generation antibody technology platforms, which it believes improve the performance of monoclonal antibodies and antibody-derived molecules. The company creates both differentiated molecules that are directed to novel cancer targets, as well as “bio-betters,” which are drugs designed to improve upon marketed medicines. The combination of MacroGenics’ technology platforms and antibody engineering expertise has allowed the company to generate promising product candidates and enter into several strategic collaborations with global pharmaceutical and biotechnology companies.
www.macrogenics.com

Statements made in this press release that are not historical facts are forward-looking statements. 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.

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