



Protalix Initiates a Home Care Treatment Program for Gaucher Patients in the Phase III Extension Trial of prGCD

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CARMIEL, Israel, June 25, 2009 (Business Wire) -- Protalix BioTherapeutics, Inc. (NYSE-AMEX:PLX), announced today the initiation of a home care treatment program for patients enrolled in the Company's phase III extension trial of plant-cell expressed recombinant glucocerebrosidase (prGCD), the Company's lead product candidate. The phase III extension trial is a follow-on study to the Company's on-going pivotal phase III clinical trial, which is evaluating the safety and efficacy of prGCD in treatment-naïve patients of Gaucher disease, a lysosomal storage disorder in humans.

The home care treatment program allows patients in the phase III extension trial to receive intravenous treatments of prGCD in the comfort of their own home, at a physician's discretion and under the supervision of a registered nurse. Upon drug approval the Company intends to continue this program as part of a patient care program designed to assist, support and educate patients receiving prGCD therapy.

"We recently enrolled our first patient in the home care treatment program," said Dr. Einat Brill-Almon, the Company's Senior Vice President for product development. "We feel physician and patients' willingness to allow prGCD to be administered in the home setting underscores their comfort level with respect to our drug. As we continue to plan for the marketing and commercialization of prGCD, we look forward to rolling out our full patient care program."

The pivotal phase III clinical trial of prGCD is a multi-center, randomized, double-blind, parallel group, dose-ranging study to assess the safety and efficacy of prGCD in treatment-naïve patients suffering from Gaucher disease. In the trial, patients are selected randomly for one of two dosing arms and receive IV infusions of prGCD every two weeks for nine months. The primary endpoint of the study is a percent change from baseline of spleen volume after 9 months, as measured by MRI. Enrollment in this trial was completed in December 2008. The Company plans to announce top-line results of the trial and file a New Drug Application with the U.S. Food and Drug Administration in the fourth quarter of 2009.

About Protalix BioTherapeutics

Protalix is a biopharmaceutical company. Its goal is to become a fully integrated biopharmaceutical company focused on the development and commercialization of proprietary recombinant therapeutic proteins to be expressed through its proprietary plant cell based expression system. Protalix's ProCellEx(TM) presents a proprietary method for the expression of recombinant proteins that Protalix believes will allow for the cost-effective, industrial-scale production of recombinant therapeutic proteins in an environment free of mammalian components and viruses. Protalix is conducting a Phase III pivotal study for its lead product candidate, prGCD, to be used in enzyme replacement therapy for Gaucher disease, a lysosomal storage disorder in humans. Protalix has reached an agreement with the United States Food and Drug Administration on the final design of the pivotal Phase III clinical trial through the FDA's Special Protocol Assessment (SPA) process. Protalix has completed enrollment for this study and is treating patients in its pivotal Phase III clinical trial in North America, South America, Israel, Europe and South Africa. The study is monitored by an independent Data Monitoring Committee, including experts in the field, who monitor the on-going safety data, which has recently held their last scheduled meeting before the end of the trial. No serious adverse events have been reported in the study. Protalix is also advancing additional recombinant biopharmaceutical drug development programs.

Safe Harbor Statement:

To the extent that statements in this press release are not strictly historical, all such statements are forward-looking, and are made pursuant to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. These statements are based on our current beliefs and expectations as to such future outcomes. Drug discovery and development involve a high degree of risk. Factors that might cause such a material difference include, among others, risks relating to the successful preclinical development of our product candidates, the completion of clinical trials, the review process of the FDA, foreign regulatory bodies and other governmental regulation, the identification of lead compounds, the risk that we may fail to satisfy certain conditions relating to grants we have received from the Office of the Chief Scientist of Israel's Ministry of Industry and Trade which may lead to our being required to refund grants previously received together with interest and penalties, the risk that the Office of the Chief Scientist may not deliver to us all of the funds awarded to us, uncertainties related to the ability to attract and retain partners for our technologies and products under development and other factors described in our filings with the Securities and Exchange Commission. The statements are valid only as of the date hereof and we disclaim any obligation to update this information.

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