Protalix BioTherapeutics Announces First Patient Enrolled in Open-Label, Switchover Trial of prGCD for the Treatment of Gaucher Disease

December 19, 2008

CARMIEL, Israel, December 19, 2008 (Business Wire) -- Protalix BioTherapeutics, Inc. (Amex: PLX), announced today enrollment of the first patient in a worldwide, multi-center, open-label, switchover trial to assess the safety and efficacy of prGCD. prGCD is the Company's proprietary plant cell expressed recombinant form of human glucocerebrosidase (GCD) that is in development for the treatment of Gaucher disease, a rare and serious lysosomal storage disorder in humans. The trial is designed to include 15 patients with Gaucher disease that are currently undergoing enzyme replacement therapy with imiglucerase (Cerezyme).

Patients that are eligible for the switchover trial will be evaluated to establish the stability of their disease. In the trial, patients with stable disease will be switched from intravenous imiglucerase treatment every two weeks to intravenous infusions of prGCD every two weeks for a nine-month period. The prGCD dose administered to each patient will be equal to the patient's previous imiglucerase dose and the infusions will be administered at selected investigational sites. At the end of the nine-month treatment period, all eligible patients will be offered the opportunity to enroll in the Company's on-going extension study.

"We are pleased to announce the initiation of our switchover trial," said Dr. Einat Brill-Almon, Vice President of Product Development at Protalix BioTherapeutics. "While this trial is not required by the FDA for the approval of prGCD, we believe the results of the trial will demonstrate the safe and efficacious transition of Gaucher patients, who are currently undergoing other treatments, to our novel drug. Data from this trial should provide additional confidence to physicians regarding our treatment for Gaucher disease and provide support for the widespread use of prGCD."

prGCD is also currently being evaluated in a pivotal phase III, multi-center, randomized, double-blind, parallel group, dose-ranging trial to assess the safety and efficacy of prGCD in naive patients suffering from Gaucher disease. The Company has completed patient enrollment in the phase III clinical trial and plans to announce top-line results in the second half of 2009. The Company expects to file a New Drug Application with the United States 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. 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. 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, 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, the identification of lead compounds, the successful preclinical development of our products, the completion of clinical trials, the review process of the FDA, foreign regulatory bodies and other governmental regulation, 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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