



Protalix BioTherapeutics to Initiate an Open-Label Extension Study for the Phase III Clinical Trial of prGCD

June 3, 2008

CARMIEL, Israel, June 3, 2008 (Business Wire) -- Protalix BioTherapeutics, Inc. (Amex: PLX), today announced that it intends to initiate a double-blind, follow-on extension study as part of the Company's on-going phase III clinical trial of its lead product candidate, prGCD, a proprietary plant cell expressed recombinant form of human Glucocerebrosidase (GCD) for the treatment of Gaucher disease, a lysosomal storage disorder in humans.

Eligible patients who have successfully completed treatment as part of the pivotal phase III clinical trial will be offered the opportunity to continue to be treated with prGCD at the same dose that they received in the trial. The objective of the proposed extension study is to compile additional information relating to the long term safety and efficacy of prGCD.

"We expect to enroll our first patient in the extension study in June," said Dr. David Aviezer, President and Chief Executive Officer of Protalix BioTherapeutics. "In addition, enrollment in our pivotal phase III clinical trial continues to progress and we are happy to announce that we have commenced recruitment at our European clinical sites, including the Royal Free Hospital of London, United Kingdom."

"We are encouraged by the clinical results to date, and look forward to reporting the results of the phase III clinical trial when they become available" said Professor Ari Zimran, M.D., Director of the Gaucher Clinic at Shaare Zedek Medical Center in Jerusalem and Principal Investigator for the trial. "The Gaucher disease community has a keen interest in developing new treatment options, particularly treatments that will be less expensive." Professor Zimran is a member of the Company's Scientific Advisory Board.

The pivotal phase III clinical trial of prGCD is a multi-center, randomized, double-blind, parallel group, dose-ranging trial to assess the safety and efficacy of prGCD in 30 naive patients suffering from Gaucher disease. In the trial, patients are selected randomly for one of two dosing arms and receive IV infusions every two weeks for nine months. The primary endpoint of the study is the change in spleen volume from baseline, as measured by MRI.

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 enrolling and treating patients in its pivotal phase III clinical trial in Israel, the United States and other locations for its lead product candidate, prGCD, for its enzyme replacement therapy for Gaucher disease, a lysosomal storage disorder in humans, and 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 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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