Protalix Holds Pre-NDA Meeting with FDA for prGCD

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CARMIEL, Israel, July 14, 2009 (Business Wire) -- Protalix BioTherapeutics, Inc. (NYSE-Amex:PLX), announced today that the Company held a pre-NDA meeting with the U.S. Food and Drug Administration (FDA). The purpose of the meeting was to discuss the Company's proposed new drug application (NDA) submission for prGCD, the Company's proprietary plant-cell expressed recombinant form of glucocerebrosidase, for the treatment of Gaucher disease and to confirm the clinical, nonclinical and chemistry requirements for the proposed NDA filing. prGCD, the Company's lead product candidate, is currently the subject of a pivotal Phase III clinical trial being conducted under the FDA's Special Protocol Assessment (SPA) for the treatment of Gaucher disease. Gaucher disease is a rare and serious lysosomal storage disorder in humans with severe and debilitating symptoms.

"This meeting gives us confidence that we will be able to submit the NDA as planned and brings us one step closer to our goal of making prGCD commercially available to Gaucher disease patients through their treating physicians," said Dr. David Aviezer, President and Chief Executive Officer. "We look forward to announcing the results of our ongoing pivotal Phase III clinical trial for prGCD in the fourth quarter of 2009 and anticipate submitting the NDA before the end of the year."

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 material differences 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, including the FDA's review of any filings we make in connection with the treatment protocol; delays in the FDA's or other health regulatory authorities' approval of any applications we file or refusals to approve such filings; refusals by such regulatory authority to approve the marketing and sale of a drug product even after acceptance of an application we file for any such drug product; 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 FDA might not approve the treatment protocol that the Company intends to file and, if such treatment protocol is filed and approved, prGCD might be provided only to a limited number of patients and only for a limited time. Pharmaceutical and biotechnology companies have suffered significant setbacks in advanced clinical trials, even after promising results in earlier clinical trials or in preliminary findings for such clinical trials. The approval by the FDA of a treatment protocol with respect to prGCD will not have any effect on the FDA's approval of any NDA filed by the Company with respect to prGCD, if any. The statements are valid only as of the date hereof and we disclaim any obligation to update this information.

Contact:
Marcy Nanus
The Trout Group, LLC
Telephone: 646-378-2927
Email: mnanus@troutgroup.com