



Protalix Receives FDA Fast Track Designation for prGCD

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CARMIEL, Israel, August 25, 2009 (Business Wire) -- Protalix BioTherapeutics, Inc. (NYSE-Amex:PLX), announced today that it has received Fast Track Designation from the U.S. Food and Drug Administration (FDA) for prGCD, the Company's proprietary plant-cell expressed recombinant form of glucocerebrosidase (GCD) for the treatment of Gaucher disease.

Fast Track designation is an FDA approved process that facilitates the development and expedites the review of drugs to treat serious diseases and fill an unmet medical need with the goal of getting important new treatments to patients earlier. This process allows a company to file the sections of the New Drug Application (NDA) as they become available instead of filing all the sections at once. It also enables the agency to commence its review and proceed on a rolling basis as the additional sections are completed and submitted for review. Protalix plans to submit the first section of the rolling NDA for prGCD, allowed under the Fast Track process, in the very near future.

Protalix expects to complete the Company's Phase III trial of prGCD for the treatment of Gaucher's disease in September, to report top-line results in October and to complete the NDA filing before the end of the year. Additionally, the Company has initiated a treatment protocol that allows physicians and other care-providers to treat Gaucher disease patients in the United States and additional countries world-wide with prGCD while the drug is still under investigation.

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 rare and serious lysosomal storage disorder in humans with severe and debilitating symptoms. Protalix and the U.S. Food and Drug Administration agreed 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 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 authorities 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. Under the approved treatment protocol, 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 FDA's approval of the treatment protocol for prGCD or the fast track approval will not have any effect on the FDA's approval of any NDA we filed with respect to prGCD, if any, and the review by the FDA of any data from the Phase III clinical development programs in connection with the approval of the treatment protocol will not have any effect on the FDA's subsequent review of our complete Phase III clinical trial data in the future. The statements are valid only as of the date hereof and we disclaim any obligation to update this information.

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