



Protalix BioTherapeutics Announces Positive Top-line Results from its Phase III Clinical Trial of UPLYSO™ for the Treatment of Gaucher Disease

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CARMIEL, Israel, October 15, 2009 (Business Wire) -- Protalix BioTherapeutics, Inc. (NYSE-Amex: PLX), announced today positive top-line results from the Company's pivotal Phase III clinical trial of UPLYSO (taliglucerase alfa, previously referred to as prGCD) in treatment naive patients diagnosed with Gaucher disease.

The trial met its primary endpoint, mean reduction in spleen volume after nine months compared with baselines, in both 60 U/kg dose and in the lower 30 U/kg dose treatment groups ($P < 0.0001$). The primary endpoint was stipulated in the Special Protocol Assessment (SPA) agreed on by the Company and the U.S Food and Drug Administration (the "FDA") prior to the commencement of the trial. Additionally, the primary endpoint was observed already after six months of treatment in both treatment groups.

Statistically significant improvements compared with baselines were also observed in the secondary endpoints, including increase in hemoglobin level, decrease in liver size and increase in platelet count at the 60 U/kg dose.

Statistically significant improvements compared with baselines were observed in hemoglobin level and liver size and significant nominal elevation in platelet count in the lower dose of 30 U/kg.

The safety analysis for both doses showed that UPLYSO was well tolerated and no serious adverse events were reported. Only 6% of patients in the trial developed antibodies to UPLYSO during the study. None of the patients in the trial developed neutralizing antibodies to UPLYSO. Only 6% of the patients in the trial experienced hypersensitivity.

Most adverse events were mild in intensity and not drug related and were transient in nature.

The Company plans to present more comprehensive results in the near future, and at upcoming medical meetings.

"Clinical studies with UPLYSO to date demonstrate very encouraging efficacy results with a high safety profile and a low rate of antibody formation," said Professor Ari Zimran, M.D. Director of the Gaucher Clinic at Shaare Zedek Medical Center in Jerusalem and Coordinating Investigator of the Company's pivotal Phase III trial of UPLYSO. "The results of this pivotal trial suggest that UPLYSO has the potential to become an attractive treatment alternative for Gaucher disease patients".

"We are extremely pleased with the top line Phase III safety and efficacy results for UPLYSO for the treatment for Gaucher disease," said Dr. David Aviezer, President and Chief Executive Officer. "We expect to complete the ongoing rolling New Drug Application (NDA) submission for marketing clearance with FDA before the end of this year. In addition, these results further validate our ProCellEx platform for the expression of safe and efficacious human therapeutic proteins in plant cell cultures, and sets the ground for many other lucrative opportunities"

Additional Study Details

The Phase III clinical trial for UPLYSO was a nine month, randomized, double-blind, parallel group, dose-ranging safety and efficacy study in patients with Gaucher disease. Patients were randomized to receive either 60 units/kg or 30 units/kg of UPLYSO administered intravenously once every two weeks. A total of 31 patients were enrolled at 11 centers in Europe, North America, South America, Israel and South Africa.

The FDA granted UPLYSO orphan product designation and fast track development status and was developed under a Special Protocol Assessment (SPA). The Company is currently making UPLYSO available to Gaucher disease patients in the U.S. and other countries under an Expanded Access Program approved by the FDA.

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 successfully completed a pivotal Phase III clinical trial for its lead product candidate, UPLYSO, 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 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 regulatory bodies, 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. Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced or late-stage clinical trials, even after obtaining promising earlier trial results or in preliminary findings for such clinical trials. Further, even if favorable testing data is generated by clinical trials of drug products, the FDA may not accept or approve an NDA filed by a pharmaceutical or biotechnology company for such drug product. Failure to obtain FDA approval of any of our drug candidates in a timely manner, if at all, will severely undermine our business and results of operation by reducing our potential marketable products and our ability to generate corresponding product revenues. Under our approved treatment protocol, UPLYSO might be provided only to a limited number of patients and only for a limited time. The FDA's approval of the treatment protocol or the fast track designation will not have any effect on the FDA's approval of any NDA we file with respect to UPLYSO, if any, and the review by the FDA of any data from our 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 in this release are valid only as of the date hereof and we disclaim any obligation to update this information.

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