Protalix Announces New Clinical Data on Taliglucerase Alfa to be Presented at the WORLD Lysosomal Disease Network Symposium

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CARMIEL, Israel, Feb. 9, 2012 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE AMEX:PLX) (TASE:PLX), announced today that new clinical data on taliglucerase alfa will be presented at the 8th Annual Meeting of the Lysosomal Disease Network: WORLD Symposium 2012 being held February 8-10 in San Diego, California. Taliglucerase alfa is the Company's proprietary plant cell expressed recombinant form of human Glucocerebrosidase (GCD), which is being developed for the treatment of Gaucher disease.

Professor Ari Zimran, M.D., Director of the Gaucher Clinic, Shaare Zedek Medical Center, Jerusalem, Israel, is presenting long-term safety and efficacy data from the Company's double-blind, follow-on extension study of taliglucerase alfa for the treatment of Gaucher disease in naïve patients. Eligible patients who completed nine months of treatment in the Company's pivotal phase III clinical trial were offered the opportunity to participate in the extension study and continue to receive taliglucerase alfa at the same dose they received in the phase III clinical trial for an additional 15 months in a blinded manner. Accordingly, the extension trial included two treatment groups; one treated with a 60 U/kg dose and the other with a 30 U/kg dose. The major endpoints of the study were spleen volume, liver volume, hemoglobin concentration, platelet count, and chitotriosidase activity. Twenty-six patients were enrolled in the extension trial which was performed in centers throughout Europe, Israel, North America, South America and South Africa.

Patients treated with taliglucerase alfa in the extension trial continued to demonstrate a statistically significant reduction in mean spleen volume after 24 months, compared with baseline, in both treatment groups. Both dosage groups demonstrated statistically significant mean reductions in spleen volume; reductions of 54.0% ($p<0.0001$) in the 60 U/kg group and of 41.0% ($p<0.0001$) in the 30 U/kg group. Statistically significant improvements were also observed in all secondary end points. Both groups demonstrated statistically significant mean reductions in liver volume; reductions of 17.5% ($p<0.0003$) in the 60 U/kg group and of 20.6% ($p<0.0001$) in the 30 U/kg group. Patients with Hepatomegaly demonstrated a reduction in liver volume of 25.2% ($p<0.0001$).

Statistically significant mean increases in hemoglobin concentration were also demonstrated by both groups; mean increases from baseline (from 11.6 g/DL to 13.9 g/DL ($p<0.0020$)) (25.8%) in the 60 U/kg group and mean increases from baseline (from 12.4 g/DL to 13.6 g/DL ($p<0.0314$)) (13.2%) in the 30 U/kg group. Anemic patients demonstrated a mean increase from baseline in hemoglobin concentration (from 9.5 g/DL to 12.9 g/DL ($p<0.0013$)) (40.8%).

The data also demonstrated statistically significant mean increases in platelet count for both groups; increases from 69,043 to 141,071 ($p<0.0016$) in the 60 U/kg group and from 64,900 to 93,333 ($p<0.0105$) in the 30 U/kg group.

Last, statistically significant mean reductions in chitotriosidase activity were demonstrated by both groups; a reduction of 76% ($p<0.0001$)) in the 60 U/kg group and of 61% ($p<0.0001$) in the 30 U/kg group.

"Pivotal and follow-up clinical studies of taliglucerase alfa to date demonstrate that taliglucerase alfa may be an effective treatment for Gaucher disease," said Dr. Ari Zimran. "The results of this 24 month extension trial suggest that taliglucerase alfa has the potential to become a treatment alternative for Gaucher disease patients should it be approved."

The safety analysis presented for both treatment groups demonstrates that taliglucerase alfa was well tolerated, and no drug related serious adverse events were reported. Two patients who participated in the extension trial developed neutralizing IgG antibodies that were determined to be positive in an in vitro assay, and were determined to be negative in a cell-based assay. In addition, one patient in the 60 U/kg dose group experienced a hypersensitivity reaction during month 10 of treatment. Treatment of this patient has been continued with premedication for an additional 32 months without any treatment related adverse event reported.

Gregory Pastores, M.D., Professor of Neurology and Pediatrics and Director of the Neurogenetics Laboratory at the New York University School of Medicine, is presenting at the WORLD 2012 Symposium the full results of all adult patients that participated in the Company's multi-center, open-label, nine month switchover trial of taliglucerase alfa for the treatment of Gaucher disease. In the switchover trial, patients with stable disease were switched from treatment via intravenous infusions of imiglucerase (Cerezyme (R)) to intravenous infusions of taliglucerase alfa every two weeks at an equivalent dose to the patient's previous imiglucerase dose. Twenty-six adult patients were enrolled in the switchover trial which was performed in centers throughout Europe, Israel, North America and Australia.

The results of the switchover trial demonstrate that over a nine-month treatment period of the study, patients remained stable with regard to the efficacy endpoints--spleen volume, liver volume, platelet count and hemoglobin concentration--after switching to taliglucerase alfa from imiglucerase. The safety analysis presented for the switchover trial demonstrates that taliglucerase alfa was well tolerated, and no drug related serious adverse events were reported. One patient developed neutralizing IgG antibodies that were determined to be positive in an in vitro assay, and were determined to be negative in a cell-based assay. Another patient experienced a hypersensitivity reaction, which was treated in a physician's office and resolved. The patient declined to continue infusions with premedication.

"The current findings are in accord with the interim observations made last year, which revealed maintenance of clinical benefit in patients switched from imiglucerase to taliglucerase across all doses. Additionally, all drug-related adverse effects were mild or moderate and transient in nature," said Dr. Gregory Pastores.

Last, Laura van Dussen, M.D., of the Academic Medical Center, University of Amsterdam, is presenting long term bone marrow responses, as measured by Quantitative Chemical Shift Imaging (QCSI) MRI, following treatment of Gaucher disease patients with taliglucerase alfa. Eight patients

from the Company's pivotal and extension trial had their fat fraction evaluated by QCSI. At 24 months, seven of the eight patients demonstrated significant improvement in fat fraction from baseline. One patient remained unchanged. In addition, four patients whose score for bone was determined to be "at risk" at baseline (fat fraction <0.23) were no longer classified as "at risk" according to the protocol after 24 months of treatment with taliglucerase alfa.

Marketing applications for taliglucerase alfa have been filed in the United States, Europe, Israel, Brazil and Australia. The U.S. Food and Drug Administration Prescription Drug User Fee Act (PDUFA) target action date for taliglucerase alfa is May 1, 2012.

About Protalix

Protalix is a biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins expressed through its proprietary plant cell based expression system, ProCellEx(R). Protalix's unique expression system presents a proprietary method for developing recombinant proteins in a cost-effective, industrial-scale manner in an environment free of mammalian components and viruses. Protalix's lead compound, taliglucerase alfa, an enzyme replacement therapy for the treatment of Gaucher disease, completed phase III development. Protalix's development pipeline also includes the following product candidates: PRX-102, a modified version of the recombinant human alpha-GAL-A protein for the treatment of Fabry disease; PRX-105, a pegylated recombinant human acetylcholinesterase in development for several therapeutic and prophylactic indications, a biodefense program and an organophosphate-based pesticide treatment program; an orally-delivered glucocerebrosidase enzyme that is naturally encased in carrot cells, also for the treatment of Gaucher disease; pr-antiTNF, a similar plant cell version of etanercept (Enbrel(R)) for the treatment of certain immune diseases such as rheumatoid arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis; and others.

Forward Looking Statements

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. The terms "anticipate," "believe," "estimate," "expect" and "intend" and other words or phrases of similar import are intended to identify forward-looking statements. 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 review process of the FDA, the European Medicines Agency (EMA), other foreign regulatory bodies and other governmental regulatory bodies, including the risk that regulatory authorities may find that the data from our clinical trials and other studies is insufficient for regulatory approval; risks relating to delays in the FDA's, the EMA's or other foreign regulatory authorities' approval of any applications we file or refusals to approve such filings, including the NDA we filed with the FDA for taliglucerase alfa for the treatment of Gaucher disease; the risk that applicable regulatory authorities may refuse to approve the marketing and sale of a drug product even after acceptance of an application we file for the drug product; risks relating to the completion of our clinical trials; 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 from clinical trials of drug products, the FDA, EMA or any other foreign regulatory authority may not accept or approve an NDA filed by a pharmaceutical or biotechnology company for such drug product. Failure to obtain approval from the FDA, EMA or any other foreign regulatory authority of any of our drug candidates in a timely manner, if at all, will severely undermine our business and results of operations by reducing our potential marketable products and our ability to generate corresponding product revenues. 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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