Protalix Announces New Data on ELELYSO(TM) (taliglucerase alfa) Presented at the European Working Group on Gaucher Disease 2014 11th Meeting

June 27, 2014

CARMIEL, Israel, June 27, 2014 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE MKT:PLX) (TASE:PLX), announced today that new clinical data on ELELYSO™ (taliglucerase alfa) will be presented at the European Working Group on Gaucher Disease 2014 11th Meeting being held June 25-28 in Haifa, Israel. ELELYSO, the Company's first commercial product, is the first FDA-approved plant cell-based enzyme replacement therapy for Gaucher disease.

"This latest data from the long-term switch over use of ELELYSO in Gaucher disease patients who were previously treated with imiglucerase further extend the efficacy and safety database for ELELYSO," stated Professor Ari Zimran, M.D., Director of the Gaucher Clinic in Shaare Zedek Medical Center, Jerusalem, Israel, and a lead clinical investigator. "These findings also reinforce that ELELYSO is an attractive alternative treatment for patients previously treated with imiglucerase."

Dr. Zimran is delivering an oral presentation titled "Taliglucerase alfa in adult patients with Gaucher disease who were previously treated with imiglucerase: 36-month safety and efficacy results". This presentation will describe long-term safety and efficacy data from the Company's multi-center, open-label switchover extension trial of ELELYSO for the treatment of Gaucher disease. The Company's original switchover trial was a nine-month trial in which patients with stable disease were switched from treatment via intravenous infusions of imiglucerase (Cerezyme®) to intravenous infusions of ELELYSO every two weeks at an equivalent dose to the patient's previous imiglucerase dose. Patients who participated in the switchover trial were given the option to continue treatment with ELELYSO in the Company's switchover extension trial.

A total of 14 patients completed the 36 months of treatments with taliglucerase alfa, at which point all patients remained clinically stable. The disease parameters that were evaluated were similar to baseline after 36 months of treatment, suggesting ongoing disease stability. These parameters included levels of hemoglobin: (Base line: 13.4 g/dL- 36 Months: 13.3 g/dL), platelet count: (Base line: 167,940 /mm^3- 36 Months: 170,286 /mm^3), spleen volume (Base line: 4.6 MN- 36 Months: 3.7 MN), liver volume (Base line: 1.0 MN- 36 Months: 1.0 MN), [MN = Multiples of the Normal size according to body weight] and chitotriosidase activity (reduction of -51.5% after 36 Months). In addition, adverse events were evaluated, all treatment-related adverse effects were mild or moderate in severity and transient in nature.

The long-term safety and efficacy results demonstrate that ELELYSO has a well-established safety profile and is an effective alternative long-term treatment for adult Gaucher patients treated previously with imiglucerase.

Detailed presentations presented at the conference will be available on the Company's website, protalix.com under the Medical Presentations tab.

In addition, the full data from the initial nine-month multi-center, open-label switchover trial of ELELYSO for the treatment of Gaucher disease were just made available in the 18 June 2014 online publication of *Blood Cells, Molecules, and Diseases* in an article entitled "A Phase 3, multicenter, open-label, switchover trial to assess the safety and efficacy of taliglucerase alfa, a plant cell-expressed recombinant human glucocerebrosidase, in adult and pediatric patients with Gaucher disease previously treated with imiglucerase". The full article can be found on the journal's website at http://www.journals.elsevier.com/blood-cells-molecules-and-diseases.

Safety Information for ELELYSO™

As with any intravenous protein medicine, like enzyme replacement therapy (ERT), severe allergic reactions (including anaphylaxis) have been observed in patients treated with ELELYSO. If this occurs, ELELYSO should be immediately discontinued, and appropriate medical treatment should be initiated. Patients who have experienced anaphylaxis to ELELYSO or another ERT should proceed with caution upon retreatment.

In addition, infusion reactions (including allergic reactions)—defined as a reaction occurring within 24 hours of the infusion—were the most commonly observed reactions to ELELYSO. The most commonly observed infusion reactions were headache, chest pain or discomfort, weakness, fatigue, hives, abnormal redness of the skin, increased blood pressure, back or joint pain, and flushing. Other infusion or allergic reactions included swelling of the face, mouth, and/or throat; wheezing; shortness of breath; skin color turning blue; coughing; and low blood pressure. Most of these reactions were mild and did not require treatment.

Management of infusion reactions is based on the type and severity of the reaction. Your doctor may manage infusion reactions by temporarily stopping the infusion, slowing the infusion rate, or treating with medications such as an antihistamine and/or a fever reducer. Treatment with antihistamines and/or corticosteroids prior to infusion with ELELYSO may prevent these reactions.

Other common adverse reactions observed were upper respiratory tract infections, throat infection, flu, urinary tract infection, and pain in extremities.

As with all therapeutic proteins, including ERTs, there is a possibility of developing antibodies to ELELYSO. However, it is currently unclear whether this has an impact on the clinical response or adverse reactions. Patients with an immune response to other ERTs who are switching to ELELYSO should continue to be monitored for antibodies. Comparison of the frequency of antibodies across ERTs may be misleading. Patients who have developed infusion or immune reactions with ELELYSO or with another ERT should be monitored for antidrug antibodies when being treated with ELELYSO.

If you are pregnant, or plan to become pregnant, you should talk to your doctor about potential benefits and risks.

The health information contained herein is provided for educational purposes only and is not intended to replace discussions with a health care provider. All decisions regarding patient care must be made with a health care provider, considering the unique characteristics of the patient.

This product information is intended only for residents of the United States.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

About Protalix BioTherapeutics, Inc.

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®. Protalix's unique expression system presents a proprietary method for developing recombinant proteins in a cost-effective, industrial-scale manner. Protalix's first product manufactured by ProCellEx, taliglucerase alfa, was approved for marketing by the U.S. Food and Drug Administration (FDA) in May 2012, by Israel's Ministry of Health in September 2012, by the Brazilian National Health Surveillance Agency (ANVISA) in March 2013, by the Mexican Federal Commission for the Protection against Sanitary Risk (COFEPRIS) in April 2013, by the Australian Therapeutic Goods Administration (TGA) in May 2014 and by the regulatory authorities of other countries. Marketing applications for taliglucerase alfa have been filed in additional territories as well. Protalix has partnered with Pfizer Inc. for the worldwide development and commercialization of taliglucerase alfa, excluding Israel and Brazil, where Protalix retains full rights. Protalix's development pipeline 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-112, an orally-delivered glucocerebrosidase enzyme that is produced and encapsulated within carrot cells, for the treatment of Gaucher disease; pr-antiTNF, a similar plant cell version of etanercept (Enbrel®) for the treatment of certain immune and inflammatory diseases, such as rheumatoid arthritis, Crohn's disease, colitis, psoriasis and other autoimmune and inflammatory disorders; PRX-110 for the treatment of Cystic Fibrosis; 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," "plan" and "intend" and other words or phrases of similar import are intended to identify forward-looking statements. Drug discovery and development involve a high degree of risk. Factors that might cause material differences include, among others: failure or delay in the commencement or completion of our preclinical studies and clinical trials which may be caused by several factors, including: risks related to the commercialization efforts for taliglucerase alfa in the United States, Israel, Brazil and other countries in which it is approved for sale; risks relating to the review process of other foreign regulatory and other governmental bodies; risks relating to delays in other foreign regulatory authorities' approval of any applications filed for taliglucerase alfa or refusals to approve such filings, as well as the decisions of such regulatory authorities regarding labeling and other matters that could affect the availability of taliglucerase alfa or its commercial potential; the risk that applicable regulatory authorities may refuse to approve the marketing and sale of a drug product even after acceptance of an application filed for the drug product; the dependence on performance by third party providers of services and supplies relating to the commercialization of taliglucerase alfa; the inherent risks and uncertainties in developing drug platforms and products of the type we are developing; the impact of development of competing therapies and/or technologies by other companies and institutions; potential product liability risks, and risks of securing adequate levels of product liability and other necessary insurance coverage; and other factors described in our filings with the U.S. Securities and Exchange Commission. These forward-looking statements are based on current information that may change and you are cautioned not to place undue reliance on these forward-looking statements. The statements in this release are valid only as of the date hereof and we disclaim any obligation to update this information. All forward-looking statements are qualified in their entirety by this cautionary statement.

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