Protalix Announces ELELYSO(TM) (taliglucerase alfa) Approved in Australia for the Treatment of Gaucher Disease in Both Adult and Pediatric Patients

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CARMIEL, Israel, May 22, 2014 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE MKT:PLX) (TASE:PLX), announced today that the Australian Therapeutic Goods Administration (TGA) has granted regulatory approval to ELELYSO™ (taliglucerase alfa) for long-term enzyme replacement therapy for both adult and pediatric patients with a confirmed diagnosis of Type 1 Gaucher disease associated with at least one of the following: splenomegaly, hepatomegaly, anemia, thrombocytopenia. ELELYSO will be marketed in Australia by Pfizer Inc., the Company's commercialization partner.

Taliglucerase alfa was approved by the U.S. Food and Drug Administration in May 2012 for adults with Type 1 Gaucher disease. With this TGA decision, the drug is now licensed in ten countries and further regulatory filings are underway.

"Australia is the first country in which ELELYSO is indicated for both adult and pediatric patients as the pediatric trials were completed concurrently with the commencement of the TGA's review," said Dr. Einat Brill Almon, Protalix's Senior Vice President, Product Development. "In other countries where ELELYSO is currently approved, label expansions are being filed to include pediatric patients as well."

ELELYSO is the first plant cell-expressed enzyme replacement therapy (ERT) for the treatment of Gaucher disease. It is also the first approved plant cell-expressed drug that is derived from ProCellEx®, the Company's proprietary plant cell-based protein manufacturing system, using genetically engineered carrot cells. ELELYSO is a form of the human lysosomal enzyme, glucocerebrosidase, used to treat Gaucher disease.

"The Australian approval of ELELYSO is an important achievement and a testament to our successful partnership with Pfizer," said Dr. David Aviezer, Protalix's President and Chief Executive Officer. "We are delighted that the TGA has approved ELELYSO for the treatment of Gaucher disease, providing an alternative treatment option for these patients."

Indication for ELELYSO in the United States

ELELYSO™ (taliglucerase alfa) for injection is a hydrolytic lysosomal glucocerebroside-specific enzyme indicated for long-term enzyme replacement therapy (ERT) for adults with a confirmed diagnosis of Type 1 Gaucher disease.

Important Safety Information for ELELYSO in the United States

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 Gaucher Disease

Gaucher disease is an inherited lysosomal storage disorder in humans that affects an estimated 10,000 people worldwide and can cause severe and debilitating symptoms, including: enlargement of the liver and spleen, various forms of bone disease, easy bruising, and anemia (a low number of red blood cells). Gaucher disease consists of varying degrees of severity; it has been sub-divided into three subtypes - Types 1, 2, and 3 - according to the

presence or absence of neurological involvement. Type 1, the most common, is found at a higher frequency among individuals who are of Ashkenazi Jewish ancestry.

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®. 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, also 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. 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 and uncertainties related to the timing of a commercial launch and market acceptance of taliglucerase alfa in Australia and other countries; 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 in Australia; 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. The statements in this release are valid only as of the date hereof and we disclaim any obligation to update this information.

CONTACT: Investor Contact

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

Media Contact

Kari Watson
MacDougall Biomedical Communications
781-235-3060
kwatson@macbiocom.com

Protalix BioTherapeutics, Inc.