UPLYSO(TM) (alfataliglicerase) Approved in Brazil by ANVISA for the Treatment of Gaucher Disease

March 18, 2013

NEW YORK and CARMIEL, Israel, March 18, 2013 (GLOBE NEWSWIRE) -- Pfizer Inc. (NYSE:PFE) and Protalix BioTherapeutics, Inc. (NYSE MKT:PLX) (TASE:PLX) announced today that the Brazilian National Health Surveillance Agency (ANVISA, Agencia Nacional de Vigilancia Sanitaria) has granted regulatory approval to UPLYSO™ (alfataliglicerase) for the long-term enzyme replacement therapy for adults with a confirmed diagnosis of Type I Gaucher disease. Gaucher disease is a rare lysosomal storage disorder that affects approximately 10,000 people worldwide.

UPLYSO is known as ELELYSO™ (taliglucerase alfa) outside of Latin America. ELELYSO was approved by the United States Food and Drug Administration in May 2012 and by Israel's Ministry of Health in September 2012 for the long-term enzyme replacement therapy (ERT) for adults with a confirmed diagnosis of Type I Gaucher disease. The ANVISA approval comes after the approval of UPLYSO by the Ministry of Public Health in Uruguay in November 2012.

"ANVISA's approval of UPLYSO demonstrates Pfizer's ability to successfully bring therapies for rare diseases to the marketplace," said Diem Nguyen, Ph.D., MBA, general manager, Pfizer Biosimilars. "We are committed to the Gaucher community and look forward to continuing to work closely with our partner Protalix toward our goal of bringing UPLYSO to those living with Gaucher throughout Latin America."

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

"The approval of UPLYSO provides an important treatment option for those in Brazil using enzyme replacement therapy to manage their Gaucher disease and demonstrates the potential of our plant cell manufacturing technology," said David Aviezer, Ph.D., MBA, president and chief executive officer of Protalix BioTherapeutics.

On November 30, 2009, Protalix entered into an agreement with Pfizer to develop and commercialize taliglucerase alfa/alfataliglicerase. Under the terms of the agreement, Protalix retained the exclusive commercialization rights in Israel, while Pfizer received exclusive licensing rights for commercialization in all other markets.

Indication for UPLYSO in Brazil

UPLYSO (alfataliglicerase) is indicated for long-term enzyme replacement therapy for adults with a confirmed diagnosis of Type I Gaucher disease. The manifestations of Gaucher disease may include one or more of the following: splenomegaly, hepatomegaly, anemia, thrombocytopenia, bone disease.

Important Safety Information for UPLYSO in Brazil

As with any intravenous protein medicine, like enzyme replacement therapy (ERT), UPLYSO may cause infusion-related reactions (i.e., occurring during or shortly after infusion) and hypersensitivity reactions. If a severe allergic reaction occurs, immediate discontinuation of the alfataliglicerase infusion is recommended. Patients who experience reactions of hypersensitivity or related to the infusion, can however be managed successfully. The therapy can be continued by slowing the infusion rate, treating with medicinal products such as antihistamines, antipyretics and/or corticosteroids, and/or stopping and resuming treatment with decreased infusion rate. Pre-treatment with antihistamines and/or corticosteroids may prevent subsequent reactions.

The most commonly observed infusion reactions were headache, hypersensitivity (allergic reaction), dizziness, flushing (redness), throat irritation, nausea (qualm), pruritus (itch), erythema (redness), rash, bone pain, back pain, arthralgia (joint pain), among others.

Also, there is a possibility of developing antibodies to UPLYSO. 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 UPLYSO should continue to be monitored for antibodies. Patients who have developed infusion or immune reactions with UPLYSO or with another ERT should be monitored for antidrug antibodies when being treated with UPLYSO.

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

Indication for ELELYSO in the U.S.

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 U.S.

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.

Pfizer Inc.: Working together for a healthier world™

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more, please visit us at www.pfizer.com.

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 protein 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, ELELYSO™ (taliglucerase alfa), was approved for marketing by the U.S. Food and Drug Administration on May 1, 2012, by Israel's Ministry of Health in September 2012 and by ANVISA on March 18, 2013. It also has been approved in Uruguay. Protalix has partnered with Pfizer Inc. for the worldwide development and commercialization of ELELYSO™, excluding Israel, where Protalix retains full rights. Marketing applications for taliglucerase alfa have been filed in additional markets.

Protalix Forward Looking Statement Disclaimer

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. Forward-looking statements involve substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties related to the timing of a commercial launch in Brazil and other countries; decisions by regulatory authorities in various countries regarding whether and when to approve drug applications that have been or may be filed for taliglucerase alfa in such countries as well as their decisions regarding labeling and other matters that could affect its availability or 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; and risks related to competitive developments. The statements in this release are valid only as of the date hereof, and Protalix disclaims any obligation to update this information. These and other risks and uncertainties are detailed under the heading "Risk Factors" in Protalix's Annual Report on Form 10-K for the year ended December 31, 2012.

PFIZER DISCLOSURE NOTICE: The information contained in this release is as of March 18, 2013. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking statements about taliglucerase alfa (generic name: alfataliglicerase in Brazil, trade name: UPLYSO in Brazil) that involve substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties regarding the commercial success of UPLYSO in Brazil; decisions by regulatory authorities in various other countries regarding whether and when to approve drug applications that have been or may be filed for taliglucerase alfa in such countries as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2012 and in its reports on Form 10-Q and Form 8-K.

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