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Pfizer And Protalix BioTherapeutics Announce FDA Approval Of ELELYSO™ (taliglucerase alfa) For The Treatment Of Gaucher Disease

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Pfizer’s Supply Continuity and Gaucher Personal Support Programs Complement New Treatment Option for U.S. ELELYSO Patients

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(BUSINESS WIRE)--Pfizer Inc.(NYSE:PFE) and Protalix BioTherapeutics, Inc. (NYSE-AMEX:PLX, TASE:PLX) announced today that the United States (U.S.) Food and Drug Administration (FDA) approved ELELYSO™ (taliglucerase alfa) for injection, an enzyme replacement therapy (ERT) for the long-term treatment of adults with a confirmed diagnosis of type 1 Gaucher disease.

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

"The approval of ELELYSO is important for patients who depend on available ERT to manage their Gaucher disease. At Protalix, our passion to develop ELELYSO was strongly driven by our personal experience with family members and friends who have to live with this disease every day,” said David Aviezer, Ph.D., MBA, president and chief executive officer of Protalix BioTherapeutics. “We also believe that this great news is a recognition of our technology, which is a plant cell manufacturing system from Protalix. This technology is the production process behind ELELYSO and other Protalix product candidates.”

Supply disruptions of approved ERTs have been affecting those living with Gaucher disease since 2009 in multiple countries including the U.S. To help minimize the possibility of supply disruptions, Pfizer is launching the “Supply Continuity Program,” which will endeavor to maintain a continuously restocked 24 months of supply at various stages of production for U.S. patients prescribed ELELYSO.

With the approval of ELELYSO, Pfizer is also introducing Gaucher Personal Support (GPS), a specialized support program for people living with Gaucher disease. Through the GPS program, Pfizer will provide an assistance program covering 100 percent of prescription co-pay expenses for eligible patients on ELELYSO who

have commercial health insurance. Additionally, Pfizer will provide financial assistance for eligible patients who are uninsured or under-insured where allowed by law.

GPS is a one-stop resource for patient support and specialty pharmacy services for those taking ELELYSO. GPS staffs a dedicated team of health care specialists who are available 24/7 to help Gaucher disease patients and their families with reimbursement assistance, facilitate locating infusion services, and provide ongoing pharmacy support. Patients can call 1-855-ELELYSO (1-855-353-5976) for a free patient information kit about ELELYSO and the GPS program.

“With ELELYSO, Pfizer is proud to be making a difference in the lives of people living with Gaucher disease,” said Diem Nguyen, Ph.D., MBA, general manager, Pfizer Biosimilars. “ELELYSO is an important addition to Pfizer’s rare disease portfolio.”

There are currently two other ERTs approved for Gaucher disease in the U.S., imiglucerase and velaglucerase. Taliglucerase alfa for injection (ELELYSO) will be available to U.S. patients at a cost that will be priced at 25 percent below the cost of imiglucerase.

“I am delighted that the Gaucher community will have another treatment option. It is especially important for this group of patients who have suffered from supply shortages in recent years,” said Rhonda Buyers, CEO and executive director of the National Gaucher Foundation (NGF).

Please see Safety Information for ELELYSO below as well as the full Prescribing Information here.

ELELYSO™ Clinical Data

The approval of ELELYSO™ (taliglucerase alfa) is based on the review of Protalix's clinical development program.

In a study of 31 adult patients with Type 1 Gaucher disease naïve to enzyme replacement therapy, the safety and efficacy of ELELYSO was assessed. The trial was a nine-month, multi-center, double blind, randomized study in patients with Gaucher disease-related enlarged spleens and thrombocytopenia. Patients were randomized to receive ELELYSO at a dose of either 30 Units/kg (n=15) or 60 Units/kg (n=16). Data showed the pivotal phase III clinical trial achieved its primary endpoint as ELELYSO significantly reduced spleen volume after nine months compared to baseline in both treatment groups. Secondary endpoints of liver volume, hemoglobin and platelet counts also showed improvement.

Twenty-six patients continued to be treated with ELELYSO in an extension of this study in a blinded manner for a total treatment duration of 24 months. The data demonstrated continued improvement in the clinical parameters.

In a study of 25 patients with Type 1 Gaucher disease who were switched from imiglucerase to ELELYSO, the safety and efficacy of ELELYSO was assessed. The trial was a nine-month, multi-center, open-label, single arm study in patients who had been receiving treatment with imiglucerase at doses ranging from 11 Units/kg to 60 Units/kg for a minimum of 2 years. Imiglucerase therapy was stopped, and treatment with ELELYSO was administered every other week at the same number of units as each patient’s previous imiglucerase dose. Organ volumes and hematologic values remained stable on average through nine months of ELELYSO treatment.

The most common adverse reactions during clinical studies were infusion reactions. Other commonly observed adverse reactions in less than ten percent of patients were URTI/nasopharyngitis, pharyngitis/throat infection, headache, arthralgia, influenza/flu, UTI/pyelonephritis, back pain and extremity pain.

“The clinical trials for ELELYSO™ demonstrate that it is an effective enzyme replacement therapy for Gaucher disease. Patients and physicians now have an additional treatment option, coupled with a patient assistance program focused on auxiliary services,” said Gregory M. Pastores, MD, associate professor of Neurology and Pediatrics at the New York University School of Medicine.

Safety Information for ELELYSO™

As with any intravenous protein product, allergic reactions, some severe, were reported in the taliglucerase alfa clinical trials. A definition of anaphylaxis (as defined by Sampson et al 2006) was retrospectively applied to some of these reports. In patients who have experienced anaphylaxis during infusion with ELELYSO or with other ERT, caution should be exercised upon retreatment; appropriate medical support should be readily available.

Infusion reactions (including allergic reactions), defined as a reaction occurring within 24 hours of the infusion, were the most commonly observed reactions in patients treated with ELELYSO in clinical studies. The most commonly observed symptoms of infusion reactions were headache, chest pain or discomfort, asthenia, fatigue, urticaria, erythema, increased blood pressure, back pain and arthralgia, and flushing. Most of these reactions were mild and did not require treatment intervention.

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 ELELYSO™ (taliglucerase alfa)

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.

Pfizer and Protalix BioTherapeutics Collaboration

On November 30, 2009, Pfizer and Protalix BioTherapeutics, Inc. entered into an agreement to develop and commercialize taliglucerase alfa. Under the terms of the agreement, Protalix has retained exclusive commercialization rights in Israel, while Pfizer received exclusive licensing rights for the commercialization of ELELYSO™ in all other markets. As part of this agreement, and at the conclusion of the FDA approval process, Protalix will transfer the ELELYSO™ NDA and IND to Pfizer.

Pfizer Inc.: Working together for a healthier world®

At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world’s best-known consumer 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 the world's leading biopharmaceutical company, we also 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 about our commitments visit 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 expression system, ProCellEx(R). Protalix's unique expression system presents a proprietary method for developing recombinant proteins in a cost-effective, industrial-scale manner. Protalix's first approved product manufactured by ProCellEx, ELELYSO™ (taliglucerase alfa), an enzyme replacement therapy for the treatment of Gaucher disease, was approved for marketing by the U.S. Food and Drug Administration on May 1, 2012. Additional marketing applications for taliglucerase alfa have been filed in other countries.

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. 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 Protalix's current beliefs and expectations as to such future outcomes. Factors that might cause material differences include, among others: risks and uncertainties related to the timing of a commercial launch and market acceptance of ELELYSO™; risks relating to the review process of the European Medicines Agency (EMA), other foreign regulatory bodies and other governmental regulatory bodies; risks relating to delays in the EMA's or other foreign regulatory authorities' approval of any applications filed for ELELYSOTM or refusals to approve such filings; 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 other factors described in Protalix's filings with the Securities and Exchange Commission. The statements in this release are valid only as of the date hereof and Protalix disclaims any obligation to update this information.

PFIZER DISCLOSURE NOTICE: The information contained in this release is as of May 1, 2012. 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 information about ELELYSO that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties related to the timing of a commercial launch and market acceptance in the U.S.; decisions by regulatory authorities in other countries regarding whether and when to approve drug applications that have been or may be filed for ELELYSO 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, 2011 and in its reports on Form 10-Q and Form 8-K.

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