



Pfizer Inc. Receives Kosher Certification for Elelyso™ (taliglucerase alfa) for Injection, for the Treatment of Type 1 Gaucher Disease

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Treatment for rare inherited lysosomal storage disorder is the first prescription medication to receive kosher certification from the Orthodox Union

Pfizer Inc. (NYSE:PFE) today announced that the Orthodox Union (OU) has granted kosher certification to 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 prescription medication to be certified kosher by the OU, a milestone for the brand which was approved by the U.S. Food and Drug Administration (FDA) in May 2012.

“Type 1 Gaucher disease is a rare disease, most frequently found among individuals of Ashkenazi Jewish descent, which has a significant impact on patients and their families,” said Rory O’Connor, Pfizer’s Senior Vice President, Head of Global Medical Affairs, Innovative Pharma Business. “This certification reflects Pfizer’s commitment to all patients suffering from Type 1 Gaucher disease.”¹

ELELYSO is an FDA-approved plant-based treatment option for Type 1 adult Gaucher patients that, in addition, meets the stringent standards of kosher regulation and inspections. The OU, the most recognized certifier of kosher products worldwide, inspected the Protalix Biotherapeutics manufacturing facility in Israel in which ELELYSO is

produced to ensure that the treatment met all applicable qualifications. The criteria were met due to Protalix's innovative and proprietary manufacturing system which uses genetically engineered carrot cells grown in a simple solution of water, plant extracts, sugar, and a mixture of vitamins and minerals to produce ELELYSO.

“We are proud to grant kosher certification to ELELYSO. Gaucher disease and its treatment options are an important issue in the Jewish community, as one in 14 Ashkenazi Jews are carriers for the disease compared to the general population,”² said Rabbi Menachem Genack, CEO of OU Kosher. “In a life or death situation, Jewish law clearly sets aside the kosher status of a prescription medicine, but in other cases, it is preferable and sometimes recommended that a medicine be certified kosher. We commend Pfizer for taking this step and making this commitment to the Jewish community.”

Protalix is the first Israeli biotech firm to partner with Pfizer Inc. ELELYSO is the first FDA-approved plant cell-based recombinant therapeutic protein.

“Protalix has a close connection and deep understanding of the Gaucher community,” said Shomrat Shurtz, Senior Director of lysosomal therapeutics products, Protalix. “This is yet another example to the strong commitment from both Pfizer and Protalix to Gaucher patients.”

For more information about Gaucher disease, please visit www.ELELYSO.com.

INDICATION

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

IMPORTANT SAFETY INFORMATION

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.

Please see ELELYSO full Prescribing Information here.

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.

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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) for injection, was approved for marketing by the U.S. Food and Drug Administration 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 and by the regulatory authorities of other countries. Marketing applications for ELELYSO have been filed in additional markets as well. Protalix has partnered with Pfizer for the worldwide development and commercialization of ELELYSO, excluding Israel and Brazil, where Protalix retains full rights.

The Orthodox Union

The Orthodox Union, now in its second century of service to the Jewish community of North America and beyond, represents the fastest growing segment in Jewish life. The OU is a world leader in community and synagogue services, adult education, youth work through NCSY, political action through the IPA (Institute of Public Affairs), and advocacy for persons with disabilities through Yachad and Our Way. Its kosher certification label, the OU, is the world's most recognized kosher symbol and can be found on over 400,000 products manufactured in 80 countries around the globe.

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1 Mistry P, et al. Consequences of diagnostic delays in type 1 Gaucher disease: The need for greater awareness among hematologists-oncologists and an opportunity for early diagnosis and intervention. *American Journal of Hematology*. 2007; 82:697-701.

2 National Human Genome Research Institute (NHGRI). Learning About Gaucher Disease. Available at:

<http://www.genome.gov/25521505>. Accessed March 6, 2014

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