



European CHMP Adopts Positive Opinion for Genzyme's Cerdelga® (eliglustat) Capsules

Paris - November 21, 2014 - [Sanofi](#) and its subsidiary [Genzyme](#) announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending approval of Cerdelga® (eliglustat) capsules, an oral treatment for certain adults living with Gaucher disease type 1.

The European Commission (EC) is expected to make a final decision on granting marketing authorization for Cerdelga in the EU in the coming months. Cerdelga was approved by the U.S. Food and Drug Administration in August, and is under review by other regulatory authorities around the world.

"Today's CHMP opinion is the next step in ensuring that Cerdelga is available to eligible adults with Gaucher disease type 1 living in the European Union," said David Meeker, MD, Genzyme President and CEO. *"The standard of care for Gaucher disease is Cerezyme® (imiglucerase for injection). With the availability of an effective oral therapy, Cerdelga would offer some patients and their physicians more choice in how to manage this serious disease."*

The CHMP opinion was based on data from the Cerdelga clinical development program, which is the largest ever conducted in Gaucher disease, with approximately 400 patients treated in 29 countries. Genzyme has been researching an oral therapy for Gaucher disease for fifteen years.

The most common adverse reactions (greater than or equal to 10%) for CERDELGA are: fatigue, headache, nausea, diarrhea, back pain, pain in extremities, and upper abdominal pain.

About Gaucher Disease

Gaucher disease is an inherited condition affecting fewer than 10,000 people worldwide. People with Gaucher disease do not have enough of an enzyme, beta-glucosidase (glucocerebrosidase) that breaks down a certain type of fat molecule. As a result, lipid engorged cells (called Gaucher cells) amass in different parts of the body, primarily the spleen, liver and bone marrow. Accumulation of Gaucher cells may cause spleen and liver enlargement, anemia, excessive bleeding and bruising, bone disease and a number of other signs and symptoms. The most common form of Gaucher disease, type 1, generally does not affect the brain.

About Genzyme's Gaucher Disease Program

Driven by a long-term commitment to meeting unmet needs in the Gaucher community, Genzyme has been researching and developing treatments for those living with Gaucher disease for over 20 years. The company's first approved therapy was the world's first treatment for Gaucher disease. A few years later, Genzyme developed a next-generation enzyme replacement therapy for Gaucher disease, which is now the standard of care with unmatched years of efficacy and safety data. In 2014, Genzyme was the first to bring to market a first-line oral treatment for Gaucher disease, providing a new treatment option for patients. Genzyme will continue to serve this community and remains committed to future advancements.

About Cerdelga

Cerdelga (eliglustat), a novel glucosylceramide analog given orally, was designed to partially inhibit the enzyme glucosylceramide synthase, which results in reduced production of glucosylceramide. Glucosylceramide is the substance that builds up in the cells and tissues of people with Gaucher disease. The concept was initially developed by the late Norman Radin, PhD, from the University of Michigan. In pre-clinical studies, the molecule, developed with James A. Shayman, MD, also from the University of Michigan, showed specificity for glucosylceramide synthase. Following an extensive pre-clinical and early clinical research program, Cerdelga was studied in the largest Phase 3 clinical program ever conducted in Gaucher disease.

IMPORTANT SAFETY INFORMATION

Indications and Usage

CERDELGATM (eliglustat) capsules are indicated for the long-term treatment of adults with Gaucher disease type 1 (GD1) who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an FDA-cleared test. Patients who are CYP2D6 ultra-rapid metabolizers (URMs) may not achieve adequate concentrations of CERDELGA to achieve a therapeutic effect. A specific dose cannot be recommended for those patients whose CYP2D6 genotype cannot be determined (indeterminate metabolizers).

Important Safety Information

CERDELGA is contraindicated in the following patients due to the risk of significantly increased CERDELGA plasma concentrations which may result in prolongation of the PR, QTc, and/or QRS cardiac intervals that could result in cardiac arrhythmias: EMs or IMs taking a strong or moderate CYP2D6 inhibitor concomitantly with a strong or moderate CYP3A inhibitor and IMs or PMs taking a strong CYP3A inhibitor.

Drugs that inhibit CYP2D6 and CYP3A may significantly increase the exposure to CERDELGA; Cerdelga dose adjustment may be needed, depending on metabolizer status. See section 7 of the full Prescribing Information for more details and other potentially significant drug interactions.

Because CERDELGA is predicted to cause increases in ECG intervals at substantially elevated plasma concentrations, use is not recommended in patients with pre-existing cardiac disease, long QT syndrome, or in combination with Class IA and Class III antiarrhythmic medications.

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Only administer CERDELGA during pregnancy if the potential benefit justifies the potential risk; based on animal data, CERDELGA may cause fetal harm. Discontinue drug or nursing based on importance of drug to mother. CERDELGA is not recommended in patients with moderate to severe renal impairment or in patients with hepatic impairment.

To report SUSPECTED ADVERSE REACTIONS, contact Genzyme Corporation at (1-800-745-4447) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information, including patient Medication Guide, for additional important safety information.

Cerezyme Important Safety Information

Approximately 15% of patients have developed IgG antibodies to Cerezyme during the first year of therapy. Approximately 46% of patients with detectable IgG antibodies experienced symptoms of hypersensitivity, and these patients have a higher risk of hypersensitivity. It is suggested that patients be monitored periodically for IgG antibody formation during the first year of treatment.

Hypersensitivity has also been observed in patients without detectable IgG antibodies. Symptoms suggestive of hypersensitivity have been noted in approximately 6.6% of all patients, and anaphylactoid reactions in less than 1%. Treatment with Cerezyme should be approached with caution in patients who have exhibited hypersensitivity symptoms such as pruritus, flushing, urticarial, angioedema, chest discomfort, dyspnea, coughing, cyanosis, and hypotension. Pre-treatment with antihistamines and/or corticosteroids and a reduced rate of infusion may allow continued treatment in most patients.

In less than 1% of patients, pulmonary hypertension and pneumonia have been observed during treatment with Cerezyme. These are known complications of Gaucher disease regardless of treatment. Patients with respiratory symptoms in the absence of fever should be evaluated for the presence of pulmonary hypertension.

Approximately 13.8% of patients have experienced adverse events related to treatment with Cerezyme. Some of these are injection site reactions such as discomfort, pruritus, burning, swelling or sterile abscess at the site of venipuncture. Additional adverse reactions that have been reported include nausea, abdominal pain, vomiting, diarrhea, rash, fatigue, headache, fever, dizziness, chills, backache, and tachycardia. Transient peripheral edema has also been reported for this therapeutic class of drug.

About Genzyme, a Sanofi Company

Genzyme has pioneered the development and delivery of transformative therapies for patients affected by rare and debilitating diseases for over 30 years. We accomplish our goals through world-class research and with the compassion and commitment of our employees. With a focus on rare diseases and multiple sclerosis, we are dedicated to making a positive impact on the lives of the patients and families we serve. That goal guides and inspires us every day. Genzyme's portfolio of transformative therapies, which are marketed in countries around the world, represents groundbreaking and life-saving advances in medicine. As a Sanofi company, Genzyme benefits from the reach and resources of one of the world's largest pharmaceutical companies, with a shared commitment to improving the lives of patients. Learn more at www.genzyme.com.

About Sanofi

Sanofi, an integrated global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT: [SAN](#)) and in New York (NYSE: [SNY](#)).

Sanofi Forward Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, the Group's ability to benefit from external growth opportunities,

trends in exchange rates and prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2012. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

Contacts:

Sanofi Media Relations

Jack Cox

Tel: +33 (0) 1 53 77 94 74

E-mail: mr@sanofi.com

Sanofi Investor Relations

Sébastien Martel

Tel: +33 (0) 1 53 77 45 45

E-mail: ir@sanofi.com

Genzyme Media Relations

Lori Gorski

Tel: (617) 768-9344

E-mail: Lori.Gorski@genzyme.com