



FDA Grants Priority Review for Genzyme's Cerdelga™ (eliglustat), an Investigational Oral Therapy for Gaucher Disease

- Second Major Regulatory Filing Following EMA Acceptance in Late October -

Paris, France - December 11, 2013 - Sanofi (EURONEXT: SAN and NYSE: SNY) and its subsidiary Genzyme announced today that the Food and Drug Administration (FDA) has granted a six-month Priority Review designation to its New Drug Application (NDA) for Cerdelga™ (eliglustat), an investigational oral therapy for adult patients with Gaucher disease type 1. As previously announced, the European Medicines Agency in late October validated Genzyme's marketing authorization application (MAA) for eliglustat in the EU.

Genzyme is developing eliglustat, a capsule to be taken twice daily, to provide an effective oral treatment alternative for patients with adult Gaucher disease type 1, and to provide a broader range of treatment options for Gaucher patients and physicians. Genzyme's clinical development program for eliglustat represents the largest clinical program ever conducted in Gaucher disease, with approximately 400 patients treated in 29 countries.

"The acceptance of our applications for Cerdelga represents another important milestone in our commitment to understand and respond to the needs in the Gaucher community, providing more choice for the treatment of patients," said Genzyme's President and CEO David Meeker, M.D.

The marketing applications for Cerdelga are based on two positive Phase 3 studies for eliglustat, ENGAGE, which included patients new to therapy, and ENCORE which included patients switching from enzyme replacement therapy. The submissions also include four years of safety and efficacy data from the eliglustat Phase 2 study.

A Priority Review designation means FDA's goal is to take action on an application within 6 months compared to 10 months under standard review.

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 the enzyme, β -glucosidase (glucocerebrosidase) leading to the accumulation of its substrate, glucosylceramide. 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 eliglustat

Eliglustat an investigational new drug is a novel glucosylceramide analog given orally and was designed to partially inhibit the enzyme glucosylceramide synthase, resulting 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, MD, from the University of Michigan. In pre-clinical studies, the molecule, developed with James A. Shayman, MD, also from the University of Michigan, has shown high potency and specificity.

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.

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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.

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