



Genzyme Phase 3 Study of Oral Compound Eliglustat Tartrate for Gaucher Disease Meets Primary Endpoint

Paris, France - October 2, 2012 - Sanofi (EURONEXT: SAN and NYSE: SNY) and its subsidiary Genzyme announced today that ENGAGE, the first Phase 3 trial of its investigational oral therapy, eliglustat tartrate, in previously untreated patients with Gaucher disease type 1, met its primary endpoint. Patients treated with eliglustat tartrate had a statistically significant improvement in spleen size at nine months, compared with placebo.

Spleen volumes in eliglustat tartrate treated patients decreased from baseline by a mean of 28 percent versus a mean increase of two percent in placebo patients, for an absolute difference of 30 percent ($p < 0.0001$). In addition, all secondary endpoints were met, including improvements in hemoglobin levels and platelet levels, as well as liver volumes compared with placebo-treated individuals.

The initial safety analysis from ENGAGE suggests that eliglustat tartrate was well tolerated. There were no serious adverse events reported in the primary analysis period and no clinically meaningful differences in the related adverse events reported between the two treatment groups.

"The efficacy and safety data from our ENGAGE trial are consistent with what were observed in our Phase 2 study, continuing to suggest that eliglustat tartrate is a potent, well tolerated oral compound that may become a meaningful option for patients and physicians," said Genzyme President and Chief Executive Officer, David Meeker, M.D. *"The development of eliglustat tartrate has been underway for more than a decade and is the largest clinical program ever focused on Gaucher disease, demonstrating our ongoing commitment to innovation on behalf of this community."*

Full results from the ENGAGE study are planned for presentation at the Lysosomal Disease Network WORLD meeting, February 12-15, 2013, in Orlando, Fla. Top-line data from Genzyme's second Phase 3 registration trial, ENCORE, are expected in early 2013.

The company is developing eliglustat tartrate, a capsule taken orally, to provide a convenient treatment alternative for patients with Gaucher disease type 1, and to provide a broader range of treatment options for patients and physicians to achieve individual therapeutic goals. Currently, Genzyme's Cerezyme[®] (imiglucerase for injection), the standard of care for patients with Gaucher disease type 1, is administered through intravenous infusions.

ENGAGE is a randomized, double-blind, placebo controlled study in treatment-naïve patients with Gaucher disease type 1 and evaluated the efficacy, safety and pharmacokinetics of twice-daily dosing of eliglustat tartrate in 40 patients untreated for at least six months. The study had a primary efficacy endpoint of improvement in spleen size in individual patients treated with eliglustat tartrate compared with treatment with placebo, after the nine month study period. Patients were stratified at baseline by their spleen volume. Thirty-nine out of 40 study participants completed at least nine months of treatment. One patient in the eliglustat treated group discontinued at six months for personal reasons. At the end of nine months, patients who were on placebo were transitioned to eliglustat tartrate. After the primary analysis period



concluded, all 39 patients chose to remain on treatment. Eighteen medical centers in 12 countries in North America, South America, Europe, Asia and the Middle East are participating in this study.

Genzyme previously reported that the 12-month Phase 2 trial had met its primary composite endpoint: a clinically meaningful response in at least two of three endpoints (improvements in spleen size, hemoglobin and platelet levels) in individual patients. All patients in the ongoing Phase 2 trial have been on treatment for at least five years.

Genzyme is currently completing the second Phase 3 registration study, ENCORE. ENCORE is a randomized, open-label study for adult patients with Gaucher disease type 1, designed to compare eliglustat tartrate to Cerezyme. One-hundred sixty adult patients were enrolled in this trial. A third trial, known as EDGE is also fully enrolled, and compares once-daily with twice-daily dosing of eliglustat tartrate. Combined, these trials represent the largest clinical program ever focused on Gaucher disease, with participating sites in over 30 countries. In total, more than 370 patients are enrolled in these studies.

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, β -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 eliglustat tartrate

Eliglustat tartrate, a novel glucosylceramide analog given orally, is 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. In preclinical studies, the molecule, developed with James A. Shayman, MD, from the University of Michigan, has shown high potency and specificity. Based on its mechanism of action, which is independent of genotype, eliglustat tartrate may be a potential therapy for all patients with Gaucher disease type 1. Initiation of the Phase 2 and 3 studies of eliglustat tartrate in Gaucher disease followed an extensive pre-clinical research effort and a Phase 1 program.

Cerezyme important safety information

Approximately 15 percent of patients have developed IgG antibodies to the infused enzyme. These patients have a higher risk of hypersensitivity reaction. Therefore periodic monitoring is suggested; caution should be exercised in patients with antibodies or prior symptoms of hypersensitivity. Symptoms suggestive of hypersensitivity occurred in 6.6 percent of patients, and include anaphylactoid reaction, pruritus, flushing, urticaria, angioedema, chest discomfort, dyspnea, coughing, cyanosis and hypotension. Reactions related to Cerezyme administration have been reported in less than 15 percent of patients. Each of the following events occurred in less than two percent of the total patient population. Reported adverse events include nausea, vomiting, abdominal pain, diarrhea, rash, fatigue, headache, fever, dizziness, chills, backache and tachycardia. Adverse events associated with the route of administration include discomfort, pruritus, burning, swelling or sterile abscess at the site of venipuncture. For full prescribing information, please visit www.genzyme.com.



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, a global and diversified 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).

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, 2011. 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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