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Genzyme Announces Positive New Data from Two Phase 3 Studies for Oral Eliglustat Tartrate for Gaucher Disease

Paris, France – February 15, 2013 – Sanofi (EURONEXT: SAN and NYSE: SNY) and its subsidiary Genzyme today announced positive new data from the Phase 3 ENGAGE and ENCORE studies of eliglustat tartrate, its investigational oral therapy for Gaucher disease type 1. The results from the ENGAGE study were presented today at the 9th Annual Lysosomal Disease Network WORLD Symposium in Orlando, Fla. In conjunction with this meeting, Genzyme also released topline data from its second Phase 3 study, ENCORE. Both studies met their primary efficacy endpoints and together will form the basis of Genzyme's registration package for eliglustat tartrate.

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. Genzyme's clinical development program for eliglustat tartrate represents the largest clinical program ever focused on Gaucher disease type 1 with approximately 400 patients treated in 30 countries.

"The data presented at this year's WORLD symposium reinforce our confidence that eliglustat tartrate may become an important oral option for patients with Gaucher disease," said Genzyme's Head of Rare Diseases, Rogerio Vivaldi MD. *"We are excited about this therapy's potential and are making excellent progress in our robust development plan for bringing eliglustat tartrate to the market."*

ENGAGE Study Results:

In ENGAGE, a Phase 3 trial to evaluate the safety and efficacy of eliglustat tartrate in 40 treatment-naïve patients with Gaucher disease type 1, improvements were observed across all primary and secondary efficacy endpoints over the nine month study period. Results were reported today at the WORLD Symposium by Pramod Mistry, MD, PhD, FRCP, Professor of Pediatrics & Internal Medicine at Yale University School of Medicine, and an investigator in the trial.

The randomized, double-blind, placebo-controlled study had a primary efficacy endpoint of improvement in spleen size in patients treated with eliglustat tartrate. Patients were stratified at baseline by spleen volume. In the study, a statistically significant improvement in spleen size was observed at nine months in patients treated with eliglustat tartrate compared with placebo. Spleen volume in patients treated with eliglustat tartrate decreased from baseline by a mean of 28 percent compared with a mean increase of two percent in placebo patients, for an absolute difference of 30 percent ($p<0.0001$).

Secondary endpoints also improved:

- Platelet levels increased from baseline by an absolute difference of 41 percent compared with placebo ($P<0.0001$)
- Hemoglobin levels increased from baseline by an absolute difference of 1.2 g/dL compared with placebo ($P<0.0006$)
- Liver volume decreased from baseline by an absolute difference of seven percent compared with placebo ($P<0.0072$)

Among tertiary endpoints:

- A statistically significant improvement in total bone marrow burden was observed among patients in the eliglustat tartrate arm compared to placebo, and all other markers of bone disease showed trends towards improvement.

In the study, there were no serious adverse events reported in either treatment group. All adverse events reported were mild or moderate, with the most common being headache, arthralgia and diarrhea. One patient withdrew from the trial, for a reason not treatment-related. At the end of the nine months, patients who were on placebo were transitioned to eliglustat tartrate.

ENCORE Study Results:

ENCORE, the second Phase 3 trial in the eliglustat tartrate development program, also met its primary efficacy endpoint.

ENCORE is a multi-national, randomized, controlled, open-label, study designed to determine whether eliglustat tartrate is non-inferior to Cerezyme® (imiglucerase for injection). In the trial, 160 patients with Gaucher disease type 1 who had begun enzyme replacement therapy at least three years prior to randomization and who had reached therapeutic goals were randomized (2:1) to receive either eliglustat tartrate or Cerezyme for one year.

The primary efficacy endpoint of stability was a composite endpoint of pre-specified change criteria for each of the following parameters: spleen volume, hemoglobin levels, platelet counts, and liver volume. To meet the endpoint for stability, a patient had to remain stable in all four parameters. Eliglustat tartrate met the pre-specified criteria for non-inferiority to Cerezyme, with the majority of patients in both groups remaining stable one year after randomization (84 percent of eliglustat tartrate patients and 94 percent of Cerezyme patients).

In an additional, pre-specified, efficacy analysis of the percent change in spleen volume from baseline, a mean change of minus 6 percent was observed in the eliglustat tartrate arm compared with minus 3 percent in the Cerezyme arm. This analysis also met the criteria for non-inferiority.

With regard to secondary endpoints, after one year, nearly all patients receiving eliglustat tartrate met the stability criteria for the individual components of the composite endpoint:

- 94 percent of patients met spleen volume criteria
- 95 percent of patients met hemoglobin levels criteria
- 93 percent of patients met platelet levels criteria
- 96 percent of patients met liver volume criteria

The majority of patients had normal bone mineral density scores at study entry for total femur and lumbar spine. These scores were maintained over the 12-month study period.

In the ENCORE trial, two percent (n=2) of eliglustat tartrate patients and two percent (n=1) of Cerezyme patients discontinued treatment because of an adverse event. Over the course of one year, four adverse events were observed in the eliglustat tartrate treatment group with ≥10 percent incidence compared with Cerezyme: fatigue (14 percent overall incidence), headache (13 percent overall incidence), nausea (12 percent overall incidence), and upper abdominal pain (10 percent overall incidence). The majority of adverse events (AEs) were mild or moderate in severity for both groups. There were no serious adverse events in the study that were considered to be related to therapy by the treating physician.

The results from the ENCORE study are expected to be presented at a medical meeting in the second half of the year.

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, 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, 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. 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).

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, 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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