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Genzyme Reports Top-line Results for TENERE Study of Oral Teriflunomide in Relapsing Multiple Sclerosis

Paris, France – December 20, 2011 – Sanofi (EURONEXT: SAN and NYSE: SNY) and its subsidiary Genzyme today reported top-line results from TENERE, a Phase III clinical trial comparing the effectiveness, safety and tolerability of once-daily oral teriflunomide to interferon beta-1a (Rebif®), an approved injectable therapy, in people with relapsing forms of multiple sclerosis (RMS). The TENERE trial, which included 324 patients, is the second completed study of five efficacy studies of teriflunomide in MS, making the clinical program one of the largest and broadest of any multiple sclerosis agent under development.

No statistical superiority was observed between the Rebif and teriflunomide arms (7mg and 14mg) on risk of treatment failure, the primary composite endpoint of the study. Risk of treatment failure was defined as the occurrence of a confirmed relapse or permanent treatment discontinuation for any cause, whichever came first. In the study, 48.6 percent of patients receiving 7mg of oral teriflunomide (n=109) and 37.8 percent of patients receiving 14 mg of oral teriflunomide (n=111) reached the primary endpoint, versus 42.3 percent of patients receiving interferon beta 1-a (n=104).

The teriflunomide 14 mg daily dose (0.259) and Rebif (0.216) were not distinguishable on the endpoint of estimated annual relapse rate. The rate was higher in the 7mg arm (0.410). The percentage of patients experiencing any treatment emergent adverse events was similar across all arms of the study. The rate of permanent treatment discontinuation in the study due to a treatment emergent adverse event was higher in the Rebif arm (21.8 percent vs. 8.2 percent in the 7mg teriflunomide arm and 10.9 percent in the 14 mg teriflunomide arm).

Both the 7mg and 14mg doses of teriflunomide were safe and generally well tolerated. Most adverse events observed in the teriflunomide arms were mild in severity, including nasopharyngitis, diarrhea, hair thinning, and back pain. These occurred with a higher incidence than in the Rebif arm. The most common adverse events observed in the Rebif arm were increases in alanine aminotransferase levels, headache and flu-like symptoms. These occurred with a higher incidence than in the teriflunomide arms. There were no deaths in the trial.

Genzyme anticipates presenting detailed TENERE study findings at a forthcoming medical meeting. The company will also include the results in its application with the EMA for marketing authorization in the European Union, along with results from its successful Phase III TEMSO trial. The company expects to file an application for marketing authorization with the EMA in the first quarter of 2012. The U.S. FDA application for teriflunomide was accepted for review by the U.S. FDA in October 2011.

About the TENERE Trial

TENERE was a two-year, randomized, rater-blinded comparator study that included 324 people with RMS from 53 centers in 13 countries. Trial participants were 18 years of age or older, with an Expanded Disability Status Scale (EDSS) of 5.5 or less at the initial screening visit. Trial participants were randomized to receive oral teriflunomide, 7 mg or 14 mg, once daily, or interferon beta-1a (Rebif® 44mcg tiw new formulation) and were followed for 48 weeks. The primary endpoint was risk of failure as defined by the first occurrence of relapse or permanent study treatment discontinuation for any cause, whichever came first. Secondary outcome measures included annualized relapse rate, subject-reported fatigue as assessed by the Fatigue Impact Scale (FIS), and subject satisfaction as assessed by the Treatment Satisfaction Questionnaire for Medication (TSQM). Safety and tolerability evaluations were based on adverse events, physical examinations, vital signs and laboratory investigations. A long-term extension of TENERE is ongoing.

About Teriflunomide

Teriflunomide is an immunomodulatory, disease-modifying oral drug with anti-inflammatory properties, and is under investigation for the treatment of MS. Teriflunomide blocks the proliferation and functioning of activated T and B lymphocytes – which are thought to be especially damaging in MS – by selectively and reversibly inhibiting a critical mitochondrial enzyme. Slowly dividing or resting lymphocytes are unaffected by teriflunomide, leaving the immune system's response to infection uncompromised.

Teriflunomide is being studied in a large clinical program that is expected to include more than 4,000 trial participants in 36 countries. Five efficacy clinical trials are either completed or underway with teriflunomide, making the clinical program one of the largest and broadest of any MS agent under development. In addition to the TEMSO and TENERE trials, the Phase III, placebo-controlled trial TOWER is ongoing in people with RMS. Another Phase III study, TOPIC, is underway in early MS or CIS (clinically isolated syndrome). Teriflunomide is also being evaluated as an adjunct therapy to interferon-β in the Phase III TERACLES trial. With up to 10 years of continuous use in a Phase II extension, teriflunomide has the longest clinical experience of any investigational oral MS therapy.

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, rare diseases, consumer healthcare, emerging markets and animal health. 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 labeling and other matters that could affect the availability or commercial potential of such products candidates, the absence of guarantee that the products 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 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, 2010. 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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