



FDA Approves Genzyme's AUBAGIO® (teriflunomide), a Once-Daily, Oral Treatment for Relapsing Multiple Sclerosis

Paris, France – September 12, 2012 - Sanofi (EURONEXT: SAN and NYSE: SNY) and its subsidiary Genzyme announced today that the U.S. Food and Drug Administration (FDA) has approved AUBAGIO® (teriflunomide) as a new once-daily, oral treatment indicated for patients with relapsing forms of multiple sclerosis (MS). AUBAGIO has shown significant efficacy across key measures of MS disease activity, including reducing relapses, slowing the progression of physical disability, and reducing the number of brain lesions as detected by MRI.

"We are very excited to introduce AUBAGIO as a new treatment option that can make a difference in the lives of people with multiple sclerosis," said David Meeker, President and CEO, Genzyme. "The approval of our first MS therapy represents an important milestone for Genzyme and underscores our commitment to long-term leadership and partnership in the MS community."

The FDA approval was based on efficacy data from the TEMSO (Teriflunomide Multiple Sclerosis Oral) trial. In the Phase III TEMSO trial, AUBAGIO 14 mg significantly reduced the annualized relapse rate ($p=0.0005$) and the time to disability progression ($p=0.0279$) at two years versus placebo in patients with relapsing forms of multiple sclerosis. AUBAGIO 7 mg significantly reduced the annualized relapse rate ($p=0.0002$) in the trial.

"Many people living with MS struggle with the additional burden of injectable therapies administered daily to weekly," said Dr. Aaron E. Miller, Medical Director, The Corinne Goldsmith Dickinson Center for Multiple Sclerosis, Mount Sinai Medical Center. "The FDA's approval of AUBAGIO, a new oral treatment option, is an encouraging advancement for the MS community and may be a valuable treatment for people living with this often debilitating disease."

The ongoing AUBAGIO clinical development program, involving more than 5,000 patients in 36 countries, is amongst the largest of any MS therapy. Some patients in extension trials have been treated for up to 10 years.

"We are greatly encouraged to see a new oral therapeutic option become available to people living with MS," said Dr. Timothy Coetzee, Chief Research Officer at the National MS Society. "With collaborative research underway around the world today, this is an extremely hopeful time for anyone who is diagnosed with MS."

The AUBAGIO label includes a boxed warning citing the risk of hepatotoxicity and, teratogenicity (based on animal data).

In MS clinical studies with AUBAGIO, the incidence of serious adverse events were similar among AUBAGIO and placebo treated patients. The most common adverse events associated with AUBAGIO in MS patients included increased ALT levels, alopecia, diarrhea, influenza, nausea and paresthesia.

The labeling for AUBAGIO was also informed by the estimated 2.1 million years of patient exposure globally since the launch of leflunomide, which is indicated in the U.S. for the treatment of rheumatoid arthritis. Teriflunomide is the principal active metabolite of leflunomide. Severe liver injury including fatal liver failure has been reported in patients treated with leflunomide.



Please click <http://products.sanofi.us/aubagio/aubagio.pdf> for full Prescribing Information for once-daily oral AUBAGIO (teriflunomide), including boxed warning and contraindications, for treatment of Relapsing Multiple Sclerosis.

The AUBAGIO clinical development program in MS also included the recently reported TOWER study. TOWER assessed the efficacy and safety of once-daily, oral AUBAGIO in patients with relapsing forms of multiple sclerosis (MS). In the study, patients receiving teriflunomide 14 mg had a statistically significant reduction in annualized relapse rate and risk of disability progression. In addition, a significant reduction in annualized relapse rate was observed in patients treated with teriflunomide 7 mg compared to placebo. Adverse events observed in the trial were consistent with previous clinical trials with teriflunomide in MS. Analysis of the full TOWER data is ongoing and results will be presented at a forthcoming scientific meeting.

AUBAGIO is an immunomodulator with anti-inflammatory properties. Although the exact mechanism of action for AUBAGIO is not fully understood, it may involve a reduction in the number of activated lymphocytes in the central nervous system (CNS).

As part of its commitment to MS patients, Genzyme has developed the MS One to One™ program. MS One to One provides information about multiple sclerosis, AUBAGIO and other relevant resources and is available and staffed by dedicated MS nurses and highly trained representatives who can provide support for individuals living with MS, their health care providers, family and loved ones. For more information about these support services, call the MS One to One line at 1-855-MSOne2One (1-855-676-6326) Monday through Friday, from 8:30 a.m. to 8:00 p.m. ET. Information and support are also available at www.MSOnetoOne.com.

Marketing applications for AUBAGIO are under review by the European Medicines Agency (EMA) and other regulatory authorities.

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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Contacts:**Sanofi Media Relations**

Marisol Péron
Tel: +33 (0) 1 53 77 46 46
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

Erin Walsh
Tel: +1 617 768 6881
Mobile: +1 617 945 3628
E-mail: erin.walsh@genzyme.com

Sanofi Investor Relations

Kristen Galfetti
Tel: +1 908 981 5560
E-mail: ir@sanofi.com