genzyme
A SANOFI COMPANY

Genzyme Receives Positive CHMP Opinion in the European Union for Once-daily, Oral AUBAGIO® to Treat Relapsing-Remitting Multiple Sclerosis

– Genzyme Planning to Request Re-examination of New Active Substance Designation –

Paris, France - March 22, 2013 - Sanofi (EURONEXT: SAN and NYSE: SNY) and its subsidiary Genzyme announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion regarding the approval of once-daily, oral AUBAGIO® (teriflunomide) for the treatment of adult patients with relapsing-remitting multiple sclerosis (MS).

"The fact that AUBAGIO has demonstrated a positive effect on disability progression in two, phase III clinical studies underscores its importance as a new treatment option for relapsing-remitting MS patients," said Professor Ludwig Kappos, MD, Chair of Neurology, University Hospital, Basel, Switzerland.

There are approximately 630,000 people affected by MS in Europe. AUBAGIO is approved to treat relapsing MS in the United States and Australia.

"This positive CHMP opinion and broad recommended indication reflect the strong data from AUBAGIO's clinical development program. As we've seen from the uptake of AUBAGIO in the United States, many patients are looking for an alternative to current injectable therapies," said Genzyme CEO and President David Meeker, MD.

The CHMP did not recommend that AUBAGIO receive a new active substance (NAS) designation.

"We are very disappointed about the CHMP opinion regarding new active substance designation. We believe based on the product's characteristics and current data that AUBAGIO is a new active substance," added Meeker. *"AUBAGIO has been studied over 10 years in one of the largest and broadest clinical development programs of any MS therapy. This decision could have a detrimental impact on future scientific innovation in MS and other diseases. We are considering all options and planning to request a re-examination of the new active substance designation."*

Additional marketing applications for AUBAGIO are under review by regulatory authorities around the world.

About AUBAGIO®

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).

Indications and Usage

AUBAGIO (teriflunomide) is a once-daily, oral treatment indicated for patients with relapsing forms of multiple sclerosis (MS). AUBAGIO 14 mg 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.

Important Safety Information About AUBAGIO

The AUBAGIO U.S. 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. Teriflunomide is the principal active metabolite of leflunomide, which is indicated in the U.S. and Europe for the treatment of rheumatoid arthritis. Severe liver injury including fatal liver failure has been reported in patients treated with leflunomide.

Leflunomide has an estimated 2.1 million patient years of exposure in rheumatoid arthritis globally since its launch.

AUBAGIO is contraindicated in pregnant women and women of childbearing potential who are not using reliable contraception.

AUBAGIO is supported by a robust clinical program with more than 5,000 trial participants in 36 countries and is amongst the largest of any MS therapy. Some patients in extension trials have been treated for up to 10 years. The EU AUBAGIO submission includes efficacy data from the TOWER (Teriflunomide Oral in people With relapsing remitting multiplE scleRosis) and TEMSO (TEriflunomide Multiple Sclerosis Oral) trials.

For full prescribing information and more information about AUBAGIO, 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, 2012. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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: 617-768-6881
E-mail: Erin.Walsh@genzyme.com

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