



## European Commission Approves Genzyme's Once-Daily, Oral Multiple Sclerosis Treatment Aubagio® (teriflunomide)

**Paris, France – August XX, 2013** – Sanofi (EURONEXT: SAN and NYSE: SNY) and its subsidiary Genzyme announced today that the European Commission has granted marketing authorization for Aubagio® (teriflunomide) 14 mg, a once-daily, oral therapy indicated for the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS).

*"The fact that Aubagio 14 mg 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. *"As a new once-daily, oral treatment option with well-characterized safety and tolerability, Aubagio could be an attractive option for patients dissatisfied with traditional injectable therapies."*

The EU approval of Aubagio was based on data from the Phase III TEMSO (TEriflunomide Multiple Sclerosis Oral) and TOWER (TEriflunomide Oral in people With relapsing remitting multiple scleRosis) trials. In these trials, Aubagio significantly reduced the annualized relapse rate and the time to disability progression at two years versus placebo.

*"Aubagio's efficacy, safety and convenient dosing may provide an attractive treatment option for patients,"* said Genzyme CEO and President, David Meeker, M.D. *"Today's approval of Aubagio is another step forward for Genzyme as we work to develop important new treatments that can address the diverse needs of the MS community."*

Multiple sclerosis is estimated to affect more than 2.1 million people globally. There are approximately 630,000 people affected by MS in Europe.

The development of Aubagio reflects more than a decade of work by the Sanofi R&D organization.

Aubagio is approved to treat relapsing MS in the United States, Australia, Argentina, Chile and South Korea, and is under review by additional regulatory agencies.

### About Aubagio® (teriflunomide)

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). Aubagio is supported by one of the largest clinical programs of any MS therapy, with more than 5,000 trial participants in 36 countries. Some patients in extension trials have been treated for up to 10 years.

### EU Indication and Usage

Aubagio (teriflunomide) 14 mg is a once-daily, oral therapy indicated in the European Union for the treatment of adult patients with relapsing remitting multiple sclerosis.

### U.S. Indication and Usage

Aubagio (teriflunomide) is a once-daily, oral therapy indicated in the U.S. for the treatment of adult patients with relapsing forms of multiple sclerosis. The recommended dose of Aubagio is 7 mg or 14 mg orally once daily.

## Important Safety Information About Aubagio

The Aubagio label includes 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 patients with severe hepatic impairment, pregnant women and women of childbearing potential who are not using reliable contraception, breast feeding women, patients with immunodeficiency states, patients with significantly impaired bone marrow function or significant anaemia, leucopenia, neutropenia or thrombocytopenia, patients with severe active infection until resolution, patients with severe renal impairment undergoing dialysis and patients with hypoproteinaemia.

For full prescribing information and more information about Aubagio for EU patients, please visit: <http://ec.europa.eu/health/documents/community-register/html/alfregister.htm>

For full prescribing information and more information about Aubagio for U.S. patients, please visit: <http://products.sanofi.us/aubagio/aubagio.pdf>

## 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](http://www.genzyme.com).

Genzyme® and Aubagio® are registered trademarks of Genzyme Corporation, a Sanofi company.

## About Sanofi

Sanofi, an integrated global 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.*

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