



## Aubagio<sup>®</sup> Significantly Reduced Risk of New Clinical Relapse or MRI Lesion in Multiple Sclerosis Study

*- Data Presented at ECTRIMS Highlight Potential of Early Intervention with Aubagio To Delay Second Clinical Attack and Reduce MRI Lesion Burden -*

**Paris, France – October 3, 2013** – Sanofi (EURONEXT: SAN and NYSE: SNY) and its subsidiary Genzyme announced today positive new data from the TOPIC study of its once-daily, oral Aubagio<sup>®</sup> (teriflunomide). These new data, presented today at the 29<sup>th</sup> Congress of the European Committee for Research and Treatment in Multiple Sclerosis (ECTRIMS), include the following:

- Aubagio 14 mg significantly reduced the risk of a new clinical relapse or MRI lesion over the two-year study period. There was a 35 percent reduction among patients who received Aubagio 14 mg compared to placebo (p=0.0003).
- As measured by MRI over the two-year study period, there was a 5 percent increase in total lesion volume among patients treated with Aubagio 14 mg compared to a 28 percent increase among patients treated with placebo (p=0.0374). In addition, there was a 59 percent reduction in gadolinium-enhancing T1 lesions among patients treated with Aubagio 14 mg compared to placebo (p=0.0008).

Similar results were observed for the 7 mg dose, though the effects did not achieve statistical significance on some endpoints.

The TOPIC trial was designed to assess whether early initiation of Aubagio in patients who experienced their first neurological symptoms suggestive of MS could prevent or delay a second clinical attack, i.e., conversion to clinically definite multiple sclerosis (CDMS).

As previously announced, patients receiving Aubagio 14 mg and 7 mg in the TOPIC trial were significantly less likely than placebo to develop CDMS, the primary endpoint. Compared to placebo, Aubagio 14 mg reduced the risk of conversion to CDMS by 43 percent.

*“The findings presented today are encouraging, as they are in line with the body of evidence supporting the value in treating MS early,”* said Dr. Aaron E. Miller, Medical Director, The Corinne Goldsmith Dickinson Center for Multiple Sclerosis, Mount Sinai Medical Center. *“These results demonstrate Aubagio’s consistent efficacy and safety across a spectrum of MS patients.”*

The average duration of Aubagio exposure in TOPIC was approximately 16 months. Adverse events observed in the trial were consistent with previous clinical trials with Aubagio in MS. The most common types of adverse events reported more frequently in the Aubagio arms were ALT (Alanine aminotransferase) elevations, headache, hair thinning, diarrhea, paresthesia and upper respiratory tract infection. There were no deaths reported in either Aubagio group over the course of the study. There was one death due to suicide in the placebo arm. The rate of treatment discontinuation due to adverse events was similar across treatment arms (9.9 percent in placebo arm, compared to 12.1 percent in 7 mg Aubagio arm and 8.3 percent in 14 mg Aubagio arm).

*“We are proud to share these results, which underscore Aubagio’s potential for treating patients in the earlier stages of MS,”* said Genzyme President and CEO, David Meeker, M.D. *“This study, in addition to*

*the studies that support Aubagio's indication in relapsing remitting MS, reflects our commitment to advancing our understanding of this complex disease."*

The trial compared treatment with either 14 mg or 7 mg once-daily, oral Aubagio against placebo. This double-blind, multi-center trial enrolled 618 patients who had experienced a first acute or sub-acute, well-defined neurological event consistent with demyelination, as well as onset of MS symptoms within 90 days of randomization, and MRI scan showing two or more T2 lesions characteristic of MS.

Aubagio is approved in the U.S., EU, Australia, Argentina, Chile, South Korea, and Mexico for the treatment of relapsing forms of MS. Marketing applications for Aubagio are also under review by additional regulatory authorities globally.

### **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 the U.S., this information can be found in the boxed warning.

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 2.5 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://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002514/human\\_med\\_001645.jsp&mid=WC0b01ac058001d124](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002514/human_med_001645.jsp&mid=WC0b01ac058001d124)

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<sup>®</sup> and Aubagio<sup>®</sup> 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.*

## Contacts:

### Sanofi Media Relations

Jack Cox  
Tel: +33 (0) 1 53 77 46 46  
E-mail: [mr@sanofi.com](mailto:mr@sanofi.com)

### Sanofi Investor Relations

Sébastien Martel  
Tel: +33 (0) 1 53 77 45 45  
E-mail: [ir@sanofi.com](mailto:ir@sanofi.com)

### Genzyme Media Relations

Erin Walsh  
Tel: +1 617 768 6881  
E-mail: [Erin.Walsh@genzyme.com](mailto:Erin.Walsh@genzyme.com)

### Sanofi Investor Relations

Kristen Galfetti  
Tel: +1 908 981 5560  
E-mail: [ir@sanofi.com](mailto:ir@sanofi.com)