New Data Suggest Slowing of Cortical Gray Matter Atrophy with Sanofi Genzyme’s Aubagio® (teriflunomide) is Associated with Delayed Conversion to Clinically Definite Multiple Sclerosis

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Sanofi Genzyme, the specialty care global business unit of Sanofi, announced today new investigational data that suggest slowing of cortical gray matter volume loss (atrophy) with Aubagio® (teriflunomide) is associated with delayed conversion to clinically definite multiple sclerosis (CDMS).

The data, from the Phase III TOPIC study in patients with a first clinical episode suggestive of MS, include results from patients treated for two years in the core study and for up to four years in the study's extension. These results, from a post hoc analysis of TOPIC, will be presented today during the 7th Joint Meeting of the European and Americas Committees for Research and Treatment in Multiple Sclerosis (ECTRIMS-ACTRIMS).

Two-Year Data
Overall, Aubagio significantly reduced cortical gray matter volume (CGMV) loss over two years vs. placebo (Aubagio 7 mg, p=0.0089; Aubagio 14 mg, p=0.0052). There was a significant association of CGMV loss with conversion to CDMS. In addition, Aubagio reduced the risk of CDMS conversion.

Cortical gray matter is a part of the central nervous system that makes up the outer surface of brain tissue of the cerebral hemispheres. Gray matter is believed to be associated with cognitive function.

- There was a significant association of CGMV loss with conversion to CDMS at all time points evaluated (months 6, 12, 18 and 24). For every 1% decrease in CGMV, the percentage increase in risk of CDMS conversion was 17.5% (p=0.0007); 12.4% (p=0.0099); 14.2% (p=0.0099); and 14.5% (p=0.0005), respectively.
- A significant treatment effect of Aubagio 14 mg on the risk of CDMS conversion was observed vs. placebo at months 12, 18 and 24. Risk reduction at months 12, 18 and 24 was 46.3% (p=0.0220), 42.1% (p=0.0260) and 46.6% (p=0.0085), respectively. Risk reduction at month 6 was 50.5% (p=0.0648).
- A significant treatment effect of Aubagio 7 mg on the risk of CDMS conversion was observed vs. placebo at month 12, with a risk reduction of 48.1% (p=0.0213). Risk reduction at months 6, 18 and 24 was 36.4% (p=0.2196), 36.8% (p=0.0644) and 30.2% (p=0.1177), respectively.

Four-Year Data
To evaluate the association of CGMV loss and CDMS conversion up to four years in patients continuing in the TOPIC extension study, the total study population, regardless of treatment allocation (7 mg, 14 mg or placebo), was categorized into three groups. Group 1 (140 patients) experienced the least CGMV loss and Group 3 (94 patients) experienced the most CGMV loss. The majority of patients (251) experienced intermediate levels of CGMV loss and were placed in Group 2.

At year 4, patients in Group 1 had a 45.1% lower risk of conversion to CDMS than those in Group 3 (p=0.0104), and patients in Group 2 had a 34.5% lower risk than those in Group 3 (p=0.0361).

"The patients in this study who experienced less brain atrophy were less likely to develop clinically definite MS," said Robert Zivadinov, M.D., Ph.D., Professor of Neurology at the University of Buffalo, Buffalo, NY. "The effects of Aubagio on reducing CGMV loss and the relationship between CGMV loss and conversion to CDMS provide insight into how Aubagio may impact the early inflammatory and neurodegenerative components of MS."

In the MS clinical studies of Aubagio, including TOPIC, the incidence of serious adverse events was similar among Aubagio and placebo-treated patients.

About Aubagio® (teriflunomide)
Aubagio is approved in more than 70 countries, with additional marketing applications under review by regulatory authorities globally. More than 80,000 patients are currently being treated with Aubagio commercially worldwide.

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.

Aubagio® (teriflunomide) U.S. INDICATION
AUBAGIO® (teriflunomide) is a prescription medicine used to treat relapsing forms of multiple sclerosis (MS).

IMPORTANT SAFETY INFORMATION

DO NOT TAKE AUBAGIO IF YOU:

- Have severe liver problems. AUBAGIO may cause serious liver problems, which can be life-threatening. Your risk may be higher if you take other medicines that affect your liver. Your healthcare provider should do blood tests to check your liver within 6 months before you start AUBAGIO and monthly for 6 months after starting AUBAGIO. Tell your healthcare provider right away if you develop any of these symptoms of liver problems: nausea, vomiting, stomach pain, loss of appetite, tiredness, yellowing of your skin or whites of your eyes, or dark urine.

- Are pregnant. AUBAGIO may harm an unborn baby. You should have a pregnancy test before starting AUBAGIO. After stopping AUBAGIO, continue to use effective birth control until you have made sure your blood levels of AUBAGIO are lowered. If you become pregnant while taking AUBAGIO or within 2 years after stopping, tell your healthcare provider right away and enroll in the AUBAGIO Pregnancy Registry at 1-800-745-4447, option 2.

- Are of childbearing potential and not using effective birth control.

It is not known if AUBAGIO passes into breast milk. Your healthcare provider can help you decide if you should take AUBAGIO or breastfeed — you should not do both at the same time.

If you are a man whose partner plans to become pregnant, you should stop taking AUBAGIO and talk with your healthcare provider about reducing the levels of AUBAGIO in your blood. If your partner does not plan to become pregnant, use effective birth control while taking AUBAGIO.

- Have had an allergic reaction to AUBAGIO or a medicine called leflunomide
- Take a medicine called leflunomide for rheumatoid arthritis.

AUBAGIO may stay in your blood for up to 2 years after you stop taking it. Your healthcare provider can prescribe a medicine that can remove AUBAGIO from your blood quickly.

Before taking AUBAGIO, talk with your healthcare provider if you have: liver or kidney problems; a fever or infection, or if you are unable to fight infections; numbness or tingling in your hands or feet that is different from your MS symptoms; diabetes; serious skin problems when taking other medicines; breathing problems; or high blood pressure. Your healthcare provider will check your blood cell count and TB test before you start AUBAGIO. Talk with your healthcare provider if you take or are planning to take other medicines (especially medicines for treating cancer or controlling your immune system), vitamins or herbal supplements.

AUBAGIO may cause serious side effects, including: reduced white blood cell count — this may cause you to have more infections; numbness or tingling in your hands or feet that is different from your MS symptoms; allergic reactions, including serious skin problems; breathing problems (new or worsening) and high blood pressure. Patients with low white blood cell count should not receive certain vaccinations during AUBAGIO treatment and 6 months after.

Tell your doctor if you have any side effect that bothers you or does not go away.

The most common side effects when taking AUBAGIO include: headache; diarrhea; nausea; hair thinning or loss; and abnormal liver test results. These are not all the side effects of AUBAGIO. Tell your healthcare provider about any side effect that bothers you.

Consult your healthcare provider if you have questions about your health or any medications you may be taking, including AUBAGIO.

You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see full U.S. Prescribing Information, including boxed WARNING and Medication Guide.

About Sanofi
Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

Sanofi Genzyme focuses on developing specialty treatments for debilitating diseases that are often difficult to diagnose and treat, providing hope to patients and their families. Learn more at www.sanogenzyme.com

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1 Company data on file

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 regarding the marketing and other potential of the product, or regarding potential future revenues from the product. 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, unexpected regulatory actions or delays, or government regulation generally, that could affect the availability or commercial potential of the product, the absence of guarantee that the product will be commercially successful, the uncertainties inherent in research and development, including future clinical data and analysis of existing clinical data relating to the product, including post marketing, unexpected safety, quality or manufacturing issues, competition in general, risks associated with intellectual property and any related future litigation and the ultimate outcome of such litigation, and volatile economic conditions, as well as those risks 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, 2016. 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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