Sanofi presents new data on Aubagio® (teriflunomide)

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* New data suggest slowing of whole brain volume loss with Aubagio is associated with delayed conversion to clinically definite multiple sclerosis

* Results from a post hoc analysis showed the effects of Aubagio on reducing whole brain volume loss versus placebo over two years

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aubagio® (teriflunomide) significantly slowed whole brain volume loss (atrophy) compared with placebo in patients with a first clinical episode suggestive of multiple sclerosis (MS), according to new investigational data from a late-stage study. Additionally, in this study, the reduction of annual whole brain volume loss was associated with a delay in conversion to clinically definite MS.

These results, from a post hoc analysis of the Phase 3 TOPIC study, will be presented this week during the 34th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in Berlin, Germany.

Key Findings

- Aubagio 14 mg significantly reduced the median percentage of whole brain volume (WBV) change versus placebo at all time points evaluated (months 6, 12, 18 and 24). At month six, treatment with Aubagio (n=165) correlated with an 87.4 percent median reduction in WBV loss relative to placebo (n=154; P=0.02). At month 12, treatment with Aubagio (n=135) correlated with a 28.6 percent median reduction in WBV loss relative to placebo (n=122; P=0.03). At month 18, treatment with Aubagio (n=109) correlated with a 36.1 percent median reduction in WBV loss relative to placebo (n=92; P=0.0003). At the last evaluation (24 months), treatment with Aubagio (n=89) correlated with a 43 percent median reduction in WBV loss relative to placebo (n=69); P<0.0001).

- Annual WBV loss observed in patients had a significant impact on conversion to clinically definite MS, with a 51.7 percent increase in risk of clinically definite MS conversion for every 1 percent decrease in WBV (P<0.0001).

“These data presented at ECTRIMS show that Aubagio significantly reduced whole brain volume loss,” said Robert Zivadinov, M.D., Ph.D., Professor of Neurology at the University of Buffalo, Buffalo, NY. “These important findings demonstrate the potential effects of Aubagio on whole brain volume loss and provide insight into how this treatment may impact the early inflammatory and neurodegenerative components of MS.”

The TOPIC intent-to-treat (ITT) population of the post hoc analysis included patients receiving placebo (n=197), Aubagio 14 mg (n=214), or Aubagio 7 mg (n=203) for ≤108 weeks. Post hoc, blinded analysis of changes in WBV was evaluated using longitudinal SIENA (Structural Image Evaluation using Normalization of Atrophy) analysis.

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

Aubagio is made available to patients by Sanofi Genzyme, the specialty care business of Sanofi.

About Aubagio® (teriflunomide)
Aubagio is approved in more than 80 countries, with additional marketing applications under review by regulatory authorities globally. Aubagio is supported by one of the largest clinical programs of any MS therapy, with more than 5,000 trial participants in 36 countries, as well as a Phase IV study with more than 3,600 patients currently enrolled. More than 86,0001 patients are currently being treated with Aubagio commercially worldwide.

Aubagio® (teriflunomide) U.S. Indication
Aubagio 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-
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 may report side effects to the FDA at 1-800-FDA-1088.

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

Endnotes
(1) Company data on file

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 debilitating diseases that are often difficult to diagnose and treat, providing hope to patients and their families. Learn more at www.sanofigenzyme.com.

Sanofi, Empowering Life

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, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic conditions, the impact of cost containment initiatives and subsequent changes thereto, 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, 2017. 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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