Relapsing MS Patients Who Switched to Aubagio® (teriflunomide) Reported Increased Treatment Satisfaction in Two Clinical Studies

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Patients with relapsing multiple sclerosis who switched to Sanofi Genzyme’s Aubagio® (teriflunomide) from interferon therapy experienced improvements in treatment satisfaction, according to investigational data from two clinical studies. These results will be presented this week during the 70th annual meeting of the American Academy of Neurology (AAN) in Los Angeles, CA.

The Phase 4 Teri-PRO study and the Phase 3 TENERE extension study evaluated patient-reported treatment satisfaction as measured by the Treatment Satisfaction Questionnaire for Medication (TSQM). The TSQM includes 14 questions intended to assess patients’ satisfaction with their medication across four domains: global satisfaction, effectiveness, side effects, and convenience.

Teri-PRO Study and TENERE Extension Study Data

In the Teri-PRO study, 285 patients switched from either interferon beta-1a or interferon beta-1b to Aubagio 14 mg. These patients reported statistically significant improvements from the start of the study to week 48 across all four TSQM domains (p=0.0001 for effectiveness, p<0.0001 for global satisfaction, side effects and convenience).

In the TENERE extension study, 59 patients switched from interferon beta-1a to Aubagio 14 mg. These patients reported statistically significant improvements in the side effects and convenience domains of the TSQM from the start of the extension through week 48 (both p<0.0001), and these improvements were maintained through week 96 (p=0.0018 and p=0.0028, respectively). Global satisfaction improved significantly from baseline to week 96 (p=0.0341).

While the two patient populations were disparate with respect to demographics and disease characteristics, the overall increases in treatment satisfaction after switching to Aubagio 14 mg were similar in both studies.

“The Teri-PRO data and the TENERE extension data being presented at AAN demonstrate that patients who switched to Aubagio from interferon therapy experienced improvements in treatment satisfaction, an important patient-centered outcome, in two clinical studies,” said Patricia K. Coyle, M.D., Director of the MS Comprehensive Care Center at Stony Brook, New York. “In addition, it is encouraging that similar overall increases in treatment satisfaction were observed in both studies, despite the two patient populations being quite different, particularly in terms of age and disease duration.”

In the Teri-PRO study, the most common adverse events (AEs) reported in ≥5 percent of patients were hair thinning, diarrhea, nausea, headache, urinary tract infection, alanine aminotransferase (ALT/liver enzyme) increase, nasopharyngitis, and fatigue. Serious AEs reported in ≥5 percent of patients were MS relapse, hypertension, ALT increase, and urinary tract infection. In the TENERE study, common AEs (≥10 percent of patients) reported more frequently with Aubagio were diarrhea, nasopharyngitis, hair thinning, paresthesia, and back pain.

About Aubagio® (teriflunomide)

Aubagio is approved in more than 70 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.

More than 85,0001 patients are currently being treated with Aubagio commercially worldwide.

1 Company data on file

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-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.

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 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 regarding the clinical development of and potential marketing approvals for the product. Forward-looking statements are generally identified by the words “expects”, “anticipates”, “believes”, “intends”, “estimates”, “plans”, “would be” 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 of the product, 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 the product or biological application that may be filed for the product as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of the product, the absence of guarantee that the product if approved will be commercially successful, risks associated with intellectual property, future litigation, the future approval and commercial success of therapeutic alternatives, 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-