Relapsing MS Patients Who Received Aubagio® (teriflunomide) Experienced a Reduced Risk of Relapse Regardless of Prior Treatment Status in a Post-Hoc Analysis

**Release Date:**
Monday, May 6, 2019 9:15 am EDT

**Terms:**

**Dateline City:**
CAMBRIDGE, Mass.

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Patients with relapsing forms of MS who received Sanofi’s Aubagio® (teriflunomide) experienced a significantly reduced risk of relapse irrespective of prior treatment status, according to investigational data from four completed clinical studies. These results will be presented this week during the 71st annual meeting of the American Academy of Neurology (AAN) in Philadelphia, PA.

The effect of Aubagio 14 mg in subgroups of patients defined by prior treatment was examined in a post-hoc analysis of four clinical studies: the Phase 2 study, and the Phase 3 TEMSO, TOWER and TENERE core studies and their extensions.

In this analysis, the patient subgroups were defined as follows:

- **Treatment naïve:** patients with no prior MS disease-modifying therapy (DMT) in the two years prior to baseline (n=1021)
- **Recently treated with Aubagio 7 mg:** patients who received Aubagio 7 mg in a core study and later switched to Aubagio 14 mg in an extension (n=353)
- **Recently treated with another DMT:** patients whose most recent prior DMT was discontinued within six months prior to baseline (n=158)
- **Previously treated:** patients whose most recent prior DMT was discontinued six months to two years prior to baseline (n=163)

In the core study period, adjusted annualized relapse rates were significantly lower in patients treated with Aubagio 14 mg (n=955) compared with placebo (n=812) regardless of prior treatment status, with a risk reduction of 35 percent, 45 percent and 34 percent in the treatment naïve, recently treated, and previously treated groups, respectively (p<0.0001; p=0.0029; p=0.0117).

In the core and extension period, overall unadjusted annualized relapse rates were low across all prior treatment groups: 0.210, 0.214, 0.281 and 0.335 in the treatment naïve, recently treated with teriflunomide 7 mg, recently treated with another DMT, and previously treated groups, respectively.

The probability of disability progression sustained for 12 weeks by year 4 was generally comparable between treatment groups (0.291, 0.250, 0.337, and 0.307) in the treatment naïve, recently treated with teriflunomide 7 mg, recently treated with another DMT, and previously treated groups, respectively. Expanded Disability Status Scale scores remained stable over time across all four groups from baseline to year 8.

"People living with MS often switch treatments several times throughout the course of their disease, and making decisions around treatment sequencing can be challenging," said Patricia K. Coyle, M.D., Director of the MS Comprehensive Care Center at Stony Brook, New York. "This analysis being presented at AAN is helpful, as it shows that relapsing MS patients treated with Aubagio experienced a significantly reduced risk of relapse, regardless of previous treatment status."

The overall occurrence of adverse events, serious adverse events and adverse events leading to treatment discontinuation was comparable between the treatment naïve, recently treated with another DMT, and previously treated groups, and was lower in the recently treated with Aubagio 7 mg. Adverse events observed in more than 10 percent of patients included alanine aminotransferase (ALT/liver enzyme) increase, headache, diarrhea, hair thinning and nausea. There were no new or unexpected safety findings.

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 98,000 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-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.

Endnote
(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 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 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.sanofigenzyme.com.

Sanofi, Empowering Life

Language:
English

Contact:
Sanofi Genzyme
Communications Contact
Erin Pascal
Tel: +1 (617) 685 5068
Erin.Pascal@sanofi.com
Sanofi Media Relations Contact
Ashleigh Koss
Tel: +1 (908) 981-8745
Ashleigh.Koss@sanofi.com