More Than 25 Data Presentations from Sanofi Genzyme’s Multiple Sclerosis Franchise to Be Featured at AAN

Release Date:
Thursday, April 19, 2018 9:00 am EDT

Terms:

Dateline City:
CAMBRIDGE, Mass.

CAMBRIDGE, Mass.--(BUSINESS WIRE)--New investigational data on Sanofi Genzyme’s marketed treatments for relapsing multiple sclerosis (MS), Lemtrada® (alemtuzumab) and Aubagio® (teriflunomide), will be presented at the 70th annual meeting of the American Academy of Neurology (AAN).

“The new data being presented at AAN continue to expand the body of knowledge on the use of Aubagio and Lemtrada, in both the clinical and real-world settings,” said Tom Snow, Sanofi Genzyme’s Global Head of Multiple Sclerosis. “As part of our long-term commitment to the MS community, we remain dedicated to finding new ways to improve patient care, with a focus on ongoing research into our current products as well as potential new treatment options.”

AAN is taking place April 21-27, 2018 in Los Angeles, California. Data presentations are as follows. All abstracts are available on the AAN website.

Sunday, April 22, 2018

Platform Session S8 (3:30 – 5:30 p.m.)
- Long-term Outcomes in Patients with Progressive Forms of Relapsing MS Treated with Teriflunomide: Real-World Evidence (Platform #003; 4:06pm)

Poster Session P1 (4:00 – 5:30 p.m.)
- Comparative Effectiveness of Teriflunomide and Dimethyl Fumarate in Patients With Relapsing Forms of MS in the Real-World Teri-RADAR Study (Poster #355)
- Treatment Experiences of Patients with MS: Results From the Global vs.MS Survey (Poster #381)

Wednesday, April 25, 2018

Platform Session S36 (3:30 – 5:30 p.m.)
- Alemtuzumab-Treated Patients Experienced Decreased MRI Disease Activity and Slowing of Brain Volume Loss Over 5 Years After Switching From SC IFNB-1a: Follow-up of Patients From CARE-MS I (TOPAZ Study) (Platform #003; 3:54 p.m.)

Poster Session P4 (5:30 – 7:00 p.m.)
- Evaluation of Teriflunomide in Children and Adolescents With Relapsing MS: TERIKIDS Phase 3 Study Design, Enrollment Update, and Baseline Data (Poster #354)
- Pregnancy Outcomes in Patients With MS Treated With Teriflunomide: Clinical Study and Postmarketing Data (Poster #361)
- Teriflunomide (Aubagio®) International Pregnancy Registry: Enrollment Update (Poster #371)

Thursday, April 26, 2018

Poster Session P5 (5:30 – 7:00 p.m.)
- Alemtuzumab Reduced MRI Lesions and the Rate of Brain Volume Loss in CARE-MS II Patients Switching From SC IFNB-1a: 5-Year Follow-up (TOPAZ Study) (Poster #031; will also be presented orally at 12:05 p.m.)
- Limited Impact of Long-term Teriflunomide Treatment on Lymphocyte Counts and Infection Rates in the Pooled TEMSO and TOWER Core and Extension Trials (Poster #357)
- Lymphocyte Counts in Patients Treated With Teriflunomide: Observations From Phase 3 Clinical Trials and the Real-World Teri-PRO Study (Poster #376)

Friday, April 27, 2018 - Poster Session P6 (4:00 – 5:30 p.m.)

Lemtrada
• Efficacy and Safety of Alemtuzumab in Real World Italian Patients Switching from Natalizumab (Poster #357)
• Efficacy of Alemtuzumab in Patients With Active Relapsing-Remitting Multiple Sclerosis Who Received Retreatment Due to Disease Activity After the Initial Two Courses: Results From the CARE-MS I Extension (Poster #362)
• Efficacy of Alemtuzumab in Patients With Active Relapsing-Remitting Multiple Sclerosis Who Received Retreatment Due to Disease Activity After the Initial Two Courses: Results From the CARE-MS II Extension (Poster #363)
• Disability Improvement Is Observed in Each Functional System in Alemtuzumab-Treated Patients With Active RRMS: Results From CARE-MS II Extension (Poster #364)
• Durable Efficacy and Safety With Alemtuzumab in CARE-MS I Patients Switching From SC IFNB-1a: 5-Year Follow-up (TOPAZ Study) (Poster #366)
• Active RRMS Patients Treated with Alemtuzumab Experience Durable Reductions in MRI Disease Activity and Slowing of Brain Volume Loss: 7-Year Follow-up of CARE-MS II Patients (TOPAZ Study) (Poster #367)
• Active RRMS Patients Treated with Alemtuzumab Experience Durable Reductions in MRI Disease Activity and Slowing of Brain Volume Loss: 7-Year Follow-up of CARE-MS II Patients (TOPAZ Study) (Poster #368)
• Durable Clinical Outcomes With Alemtuzumab in Patients With Active RRMS in the Absence of Continuous Treatment: 7-Year Follow-up of CARE-MS II Patients (TOPAZ Study) (Poster #369)
• Durable Reduction in MRI Disease Activity and Slowing of Brain Volume Loss in Alemtuzumab-Treated Patients With Active RRMS: 7-Year Follow-up of CARE-MS I Patients (TOPAZ Study) (Poster #375)
• Durable Clinical Efficacy of Alemtuzumab in Patients With Active RRMS in the Absence of Continuous Treatment: 7-Year Follow-up of CARE-MS I Patients (TOPAZ Study) (Poster #376)
• Alemtuzumab Improves Patient-reported Quality of Life Outcomes in Patients With Relapsing-remitting Multiple Sclerosis: Results From the CARE-MS I Extension Study (Poster #380)
• Alemtuzumab Improves Patient-reported Quality of Life Outcomes in Patients With Rapidly Evolving Severe Relapsing-remitting MS: Results From the CARE-MS I Extension Study (Poster #392)

Aubagio

• Evaluation of the Long-term Treatment Effect of Teriflunomide on Cognitive Outcomes and Association With Brain Volume Change: Data From TEMSO and its Extension Study (Poster #372)
• Long-term Disability Outcomes in Teriflunomide-Treated Patients in TEMSO and TOWER: An Analysis Utilizing the Topographical Model of MS (Poster #374)
• Long-term Disability Outcomes in Patients Treated With Teriflunomide for up to 14 Years: Group- and Patient-Level Data From the Phase 2 Extension Study (Poster #389)
• Long-term Efficacy and Safety Outcomes of Teriflunomide Treatment in TEMSO and TOWER (Poster #391)
• Treatment Satisfaction With Teriflunomide in Patients Switching From a Prior Disease-Modifying Therapy: Results From the Phase 3 TENERE and Phase 4 Teri-PRO Clinical Trials (Poster #396)

About Lemtrada® (alemtuzumab)

Lemtrada is approved in more than 60 countries, with additional marketing applications under review by regulatory authorities globally. Lemtrada is supported by a comprehensive and extensive clinical development program that involved nearly 1,500 patients worldwide and 5,400 patient-years of follow-up. More than 19,0001 patients have been treated with Lemtrada commercially worldwide.

Sanofi Genzyme holds the worldwide rights to alemtuzumab and has responsibility for its development and commercialization in multiple sclerosis. Bayer Healthcare receives contingent payments based on global sales revenue.

Lemtrada® (alemtuzumab) U.S. Indication

LEMTRADA is a prescription medicine used to treat adults with relapsing forms of multiple sclerosis (MS). Because of its risks, LEMTRADA is generally used in people who have tried 2 or more MS medicines that have not worked well enough. It is not known if LEMTRADA is safe and effective for use in children under 17 years of age.

Do not receive LEMTRADA if you are infected with human immunodeficiency virus (HIV).

IMPORTANT SAFETY INFORMATION

LEMTRADA can cause serious side effects including:

Serious autoimmune problems: Some people receiving LEMTRADA develop a condition where the immune cells in your body attack other cells or organs in the body (autoimmunity), which can be serious and may cause death. Serious autoimmune problems may include:

• Immune thrombocytopenia, which is when reduced platelet counts in your blood cause severe bleeding that, if not treated, may cause life-threatening problems. Call your healthcare provider right away if you have any of the following symptoms: easy bruising; bleeding from a cut that is hard to stop; heavier menstrual periods than normal; bleeding from your gums or nose that is new or takes longer than usual to stop; small, scattered spots on your skin that are red, pink, or purple

• Kidney problems called anti-glomerular basement membrane disease, which can, if untreated, lead to severe kidney
damage, kidney failure that needs dialysis, a kidney transplant, or death. Call your healthcare provider right away if you have any of the following symptoms: blood in the urine (red or tea-colored urine); swelling of legs or feet; coughing up blood.

It is important for you to have blood and urine tests before you receive, while you are receiving and every month, for 4 years or longer, after you receive your last LEMTRADA infusion.

**Serious infusion reactions:** LEMTRADA can cause serious infusion reactions that may cause death. Serious infusion reactions may happen while you receive, or up to 24 hours or longer after you receive LEMTRADA.

- You will receive your infusion at a healthcare facility with equipment and staff trained to manage infusion reactions, including serious allergic reactions, and urgent heart or breathing problems. You will be watched while you receive, and for 2 hours or longer after you receive, LEMTRADA. If a serious infusion reaction happens while you are receiving LEMTRADA, your infusion may be stopped.

Tell your healthcare provider right away if you have any of the following symptoms of a serious infusion reaction during the infusion, and after you have left the healthcare facility:

- swelling in your mouth or throat
- fast, slow, or irregular heartbeat
- trouble breathing
- chest pain
- weakness
- rash

To lower your chances of getting a serious infusion reaction, your healthcare provider will give you a medicine called corticosteroids before your first 3 infusions of a treatment course. You may also be given other medicines before or after the infusion to try to reduce your chances of having these reactions or to treat them after they happen.

**Certain cancers:** Receiving LEMTRADA may increase your chance of getting some kinds of cancers, including thyroid cancer, skin cancer (melanoma), and blood cancers called lymphoproliferative disorders and lymphoma. Call your healthcare provider if you have the following symptoms that may be a sign of thyroid cancer:

- new lump
- trouble swallowing or breathing
- swelling in your neck
- cough that is not caused by a cold
- pain in front of neck
- hoarseness or other voice changes that do not go away

Have your skin checked before you start receiving LEMTRADA and each year while you are receiving treatment to monitor for symptoms of skin cancer.

**Because of risks of autoimmunity, infusion reactions, and some kinds of cancers, LEMTRADA is only available through a restricted program called the LEMTRADA Risk Evaluation and Mitigation Strategy (REMS) Program.**

**Thyroid problems:** Some patients taking LEMTRADA may get an overactive thyroid (hyperthyroidism) or an underactive thyroid (hypothyroidism). Call your healthcare provider if you have any of these symptoms:

- excessive sweating
- unexplained weight gain
- unexplained weight loss
- feeling cold
- eye swelling
- worsening tiredness
- nervousness
- constipation
- fast heartbeat

**Low blood counts (cytopenias):** LEMTRADA may cause a decrease in some types of blood cells. Some people with these low blood counts have increased infections. Call your doctor right away if you have symptoms of cytopenias such as:

- weakness
• dark urine
• chest pain
• fast heartbeat
• yellowing of the skin or whites of the eyes (jaundice)

Serious infections: LEMTRADA may cause you to have a serious infection while you receive and after receiving a course of treatment. Serious infections may include:

• **Herpes viral infections.** Some people taking LEMTRADA have an increased chance of getting herpes viral infections. Take any medicines as prescribed by your healthcare provider to reduce your chances of getting these infections.

• **Tuberculosis.** Your healthcare provider should check you for tuberculosis before you receive LEMTRADA.

• **Hepatitis.** People who are at high risk of, or are carriers of, hepatitis B (HBV) or hepatitis C (HCV) may be at risk of irreversible liver damage.

• **Listeria.** People who receive LEMTRADA have an increased chance of getting a bacterial infection called listeria, which can lead to significant complications or death. Avoid foods that may be a source of listeria or make sure foods that may contain listeria are heated well.

These are not all the possible infections that could happen while on LEMTRADA. Call your healthcare provider right away if you have symptoms of a serious infection such as fever or swollen glands. Talk to your healthcare provider before you get vaccinations after receiving LEMTRADA. Certain vaccinations may increase your chances of getting infections.

**Inflammation of the gallbladder without gallstones (acalculous cholecystitis):** LEMTRADA may increase your chance of getting inflammation of the gallbladder without gallstones, a serious medical condition that can be life-threatening. Call your healthcare provider right away if you have any of the following symptoms:

• stomach pain or discomfort
• fever
• nausea or vomiting

**Swelling of lung tissue (pneumonitis):** Some people have had swelling of the lung tissue while receiving LEMTRADA. Call your healthcare provider right away if you have the following symptoms:

• shortness of breath
• chest pain or tightness
• cough
• coughing up blood
• wheezing

Before receiving LEMTRADA, tell your healthcare provider if you:

• are taking a medicine called Campath® (alemtuzumab)
• have bleeding, thyroid, or kidney problems
• have HIV
• have a recent history of infection
• have received a live vaccine in the past 6 weeks before receiving LEMTRADA or plan to receive any live vaccines. Ask your healthcare provider if you are not sure if your vaccine is a live vaccine
• are pregnant or plan to become pregnant. LEMTRADA may harm your unborn baby. You should use birth control while receiving LEMTRADA and for 4 months after your course of treatment
• are breastfeeding or plan to breastfeed. You and your healthcare provider should decide if you should receive LEMTRADA or breastfeed. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. LEMTRADA and other medicines may affect each other, causing side effects. Especially tell your healthcare provider if you take medicines that increase your chance of getting infections, including medicines used to treat cancer or to control your immune system.

The most common side effects of LEMTRADA include:

• rash
• headache
• thyroid problems
- fever
- swelling of your nose and throat
- nausea
- urinary tract infection
- feeling tired
- trouble sleeping
- upper respiratory infection
- herpes viral infection
- hives
- itching
- fungal infection
- joint pain
- pain in your arms or legs
- back pain
- diarrhea
- sinus infection
- mouth pain or sore throat
- tingling sensation
- dizziness
- stomach pain
- sudden redness in face, neck or chest
- vomiting

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of LEMTRADA.

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

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 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.sanogenzyme.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-looking information or statements.

Language:
English

Contact:
Sanofi Genzyme Communications Contact
Erin Pascal, +1 617-685-5068
erin.pascal@sanofi.com