More than 35 Presentations of New Investigational Data from Sanofi Genzyme’s Multiple Sclerosis Franchise to be Featured at AAN

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--)Sanofi Genzyme, the specialty care global business unit of Sanofi, today announced that new investigational data on its marketed treatments, Lemtrada® (alemtuzumab) and Aubagio® (teriflunomide), as well as data from the company’s MS pipeline, will be presented during the 68th annual meeting of the American Academy of Neurology (AAN). The meeting, being held in Vancouver, Canada, will include more than 35 platform and poster presentations of data from across Sanofi Genzyme’s MS franchise.

“Nearly 8,000 patients worldwide have now been treated with Lemtrada, which potentially offers a unique approach to treating relapsing forms of MS based on sustained effects in the absence of continuous treatment. We look forward to sharing new investigational clinical trial and real-world data at AAN to help the MS community better understand the potential benefits of this treatment,” said Carole Huntsman, Sanofi Genzyme’s Global Multiple Sclerosis Lead. “Lemtrada and Aubagio play important roles in the MS treatment landscape, and our research efforts, focused on unmet needs for relapsing and progressive forms of the disease, demonstrate our long-term commitment to people living with MS.”

Data presentations are as follows. All abstracts are available on the AAN website.

Lemtrada

- Alemtuzumab-Treated Patients with RRMS Demonstrate Durable Slowing of Brain Volume Loss Over 5 Years Despite Most Being Treatment-Free for 4 Years: CARE-MS I and II Extension Study (Platform Session S51 #001 April 21; 3:30 – 3:45 p.m. PDT)
- Treatment-Naive Patients with Active RRMS Who Received Alemtuzumab Demonstrate Durable Suppression of New MRI Lesion Formation: 5-Year Follow-Up of the CARE-MS I Study (Platform Session S51 #002 April 21; 3:45 – 4:00 p.m. PDT)
- Treatment-Naive Patients with Highly Active RRMS Demonstrated Durable Efficacy with Alemtuzumab over 5 Years (Platform Session S51 #003 April 21; 4:00 – 4:15 p.m. PDT)
- Treatment-Naive Patients with Active RRMS Demonstrate Durable Improvements in Relapse and Disability Following Treatment with Alemtuzumab: 5-Year Follow-Up of the CARE-MS I Study (Platform Session S51 #004 April 21; 4:15 – 4:30 p.m. PDT)
- Durable Efficacy in RRMS Patients Receiving Two Annual Courses of Alemtuzumab and No Additional Treatment for 4 Years: Pooled Analysis of CARE-MS I and II (Platform Session S51 #005 April 21; 4:30 – 4:45 p.m. PDT)
- Pregnancy Outcomes in Patients with RRMS Who Received Alemtuzumab in the Clinical Development Program (Platform Session S24 #008 April 18; 5:15 – 5:30 p.m. PDT)
- Incidence and Timing of Thyroid Adverse Events in Patients with RRMS Treated with Alemtuzumab through 5 Years of the CARE-MS Studies (Poster Session P2 #086 April 17; 4:00 – 5:00 p.m. PDT)
- Patients With Active RRMS and an Inadequate Response to Prior Therapy Demonstrate Durable Improvements in Relapse and Disability Following Treatment With Alemtuzumab: 5-Year Follow-up of the CAREMS II Study (Poster Session P3 #022 April 18; 5:30 – 7:00 p.m. PDT)
- Patients Who Switched From SC IFNB-1a to Alemtuzumab in the CARE-MS II Extension Study Show Durable Improvements in Clinical Outcomes (Poster Session P3 #024 April 18; 5:30 – 7:00 p.m. PDT)
- Patients Who Discontinued SC IFNB-1a and Switched to Alemtuzumab in the CARE-MS II Extension Study Show Durable Reduction in New Lesion Activity (Poster Session P3 #025 April 18; 5:30 – 7:00 p.m. PDT)
- Patients Who Discontinued SC IFNB-1a and Switched to Alemtuzumab in the CARE-MS I Extension Study Show Durable Reduction in New Lesion Activity (Poster Session P3 #026 April 18; 5:30 – 7:00 p.m. PDT)
- Durable Efficacy of Alemtuzumab Over 10 Years: Long-Term Follow-up of Patients With RRMS From the CAMMS223 Study (Poster Session P3 #053 April 18; 5:30 – 7:00 p.m. PDT)
- Long-term Responders From the CARE-MS I Study: No Evidence of Disease Activity for 4 Years Following 2 Courses of Alemtuzumab and No Further Treatment (Poster Session P3 #054 April 18; 5:30 – 7:00 p.m. PDT)
- No Evidence of Disease Activity for 4 Years Following 2 Courses of Alemtuzumab and No Further Treatment: Long-Term Responders from the CARE-MS II Study (Poster Session P3 #059 April 18; 5:30 – 7:00 p.m. PDT)
Bayer Genzyme holds the worldwide rights to alemtuzumab and has responsibility for the treatment course. Lymphocyte counts then increase over time with a responsible for the damaging inflammatory process in MS. Alemtuzumab is a monoclonal antibody that targets CD52, a protein abundant on T and B cells. Circulating T and B cells are thought to be responsible for the damaging inflammatory process in MS. Alemtuzumab depletes circulating T and B lymphocytes after each treatment course. Lymphocyte counts then increase over time with a reconstitution of the lymphocyte population that varies for the different lymphocyte subtypes.

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.

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.

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.

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

Please click here for full U.S. Prescribing Information, including boxed WARNING and Medication Guide, for additional Important Safety Information.

About Aubagio® (teriflunomide)
Aubagio is approved in more than 60 countries, with additional marketing applications under review by regulatory authorities globally. More than 50,000 people have been treated with Aubagio 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.
- Take a medicine called leflunomide for rheumatoid arthritis.
• 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.

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), vaccines, 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; serious skin problems; breathing problems (new or worsening); and high blood pressure.

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 click here for full Prescribing Information, including boxed WARNING and Medication Guide.

About Sanofi
Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients’ needs. Sanofi has core strengths in diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and Genzyme.

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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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, the Group’s ability to benefit from external growth opportunities, trends in exchange rates and prevailing interest rates, the impact of cost containment initiatives and subsequent changes thereto, the average number of shares outstanding 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, 2015. 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
Media Relations
Erin Pascal, +1 617-768-6864
erin.pascal@genzyme.com
or
Sanofi
Media Relations
Jack Cox, +33 (0) 1 53 77 46 46
mr@sanofi.com
or
Investor Relations
Sébastien Martel, +33 (0) 1 53 77 45 45
ir@sanofi.com