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

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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 for relapsing multiple sclerosis (MS), Lemtrada® (alemtuzumab) and Aubagio® (teriflunomide), will be presented during the 32nd annual meeting of the Congress of the European Committee for Research and Treatment in Multiple Sclerosis (ECTRIMS). The meeting, being held in London September 14 – 17, will feature more than 35 platform and poster presentations of data from across Sanofi Genzyme’s MS franchise.

“We are excited to present new investigational and real-world data on Aubagio and Lemtrada that further the understanding of these therapies,” said Carole Huntsman, Sanofi Genzyme’s Global Multiple Sclerosis Lead. “Aubagio and Lemtrada play important roles in the treatment of people living with relapsing MS. We are committed to a long-term partnership with the MS community, and to advancing science with the goal of addressing unmet needs among those living with this debilitating disease.”

Data presentations on Aubagio and Lemtrada are as follows. All abstracts are available on the ECTRIMS website.

Lemtrada:

- Autoimmunity in Patients Treated With Alemtuzumab for Relapsing-Remitting Multiple Sclerosis: 5-Year Follow-up of the CARE-MS Studies (Free Communications 1 #168 September 16; 9:15 – 10:15 a.m. BST)
- Alemtuzumab Provides Durable Improvements in Clinical Outcomes in Treatment-Naive Patients With Active Relapsing-Remitting Multiple Sclerosis Over 6 Years in the Absence of Continuous Treatment (CARE-MS I) (Parallel Session 11 #213 September 16; 2:00 – 3:30 p.m. BST)
- Durable Suppression of Disease Activity by Alemtuzumab in the Absence of Continuous Treatment Over 6 Years in Patients with Active Relapsing-Remitting Multiple Sclerosis and an Inadequate Response to Prior Therapy (CARE-MS II) (Poster Session 1, P681 September 15; 3:45 – 5:00 p.m. BST)
- Alemtuzumab Durably Suppresses Disease Activity Over 6 Years in Treatment-Naive Patients With Active Relapsing-Remitting Multiple Sclerosis in the Absence of Continuous Treatment (CARE-MS I) (Poster Session 1, P682 September 15; 3:45 – 5:00 p.m. BST)
- Durable Reduction in MRI Disease Activity With Alemtuzumab in Treatment-Naïve Patients With Active Relapsing-Remitting Multiple Sclerosis: 6-Year Follow-up of the CARE-MS I Study (Poster Session 1, P683 September 15; 3:45 – 5:00 p.m. BST)
- Healthcare Resource Utilisation and Costs in Patients With Active Relapsing-Remitting Multiple Sclerosis Treated With Alemtuzumab vs. SC IFNB-1a (CARE-MS II) (Poster Session 1, P370 September 15; 3:45 – 5:00 p.m. BST)
- Lymphocyte Depletion and Repopulation is Consistent Across Alemtuzumab Treatment Courses in Patients With Relapsing-Remitting Multiple Sclerosis: 6-year Analysis of Patients from the CARE-MS Studies (Poster Session 1, P654 September 15; 3:45 – 5:00 p.m. BST)
- Alemtuzumab Improves Clinical Outcomes Over 4 Years in Patients With Relapsing-Remitting Multiple Sclerosis Who Switched From SC IFNB-1a: CARE-MS II Extension Study 4-Year Follow-up (Poster Session 1, P680 September 15; 3:45 – 5:00 p.m. BST)
- Improvements in Quality of Life Over 5 Years With Alemtuzumab Are Associated With Confirmed Disability Improvement in Patients With Active Relapsing-Remitting Multiple Sclerosis Who Had an Inadequate Response to Prior Therapy (CARE-MS II) (Poster Session 1, P768 September 15; 3:45 – 5:00 p.m. BST)
- Durable Effect of Alemtuzumab on MRI Lesion Outcomes Over 5 Years in Patients With Highly Active Relapsing-Remitting Multiple Sclerosis Who Had an Inadequate Response to Prior Therapy (CARE-MS II) (Poster Session 1, P613 September 15; 3:45 – 5:00 p.m. BST)
- Alemtuzumab Significantly Improves Disability in Patients With Active Relapsing-Remitting MS and an Inadequate Response to Prior Therapy as Assessed Using a Novel, Composite Measure: Confirmed Disability Improvement-Plus: Results from CARE-MS II (Poster Session 1, P610 September 15; 3:45 – 5:00 p.m. BST)
- Efficacy and Safety of Alemtuzumab in Patients with RRMS is Durable Over 10 Years: Follow-up From the CAMMS223 Study (Poster Session 1, P679 September 15; 3:45 – 5:00 p.m. BST)
- Efficacy of Alemtuzumab is Durable Over 6 Years in Patients With Active Relapsing-Remitting Multiple Sclerosis and an
Durable Improvement in Clinical Outcomes in Treatment-Naive Patients With Relapsing-Remitting Multiple Sclerosis Who Switched From SC IFNB-1a to Alemtuzumab (CARE-MS I Extension Study 4-Year Follow-up) (Poster Session 2, P1232 September 16; 3:30 – 5:00 p.m. BST)

Alemtuzumab Durably Slows Brain Volume Loss Over 6 years in the Absence of Continuous Treatment in Patients With Active RRMS Who Were Treatment-Naive (CARE-MS I) or Had an Inadequate Response to Prior Therapy (CARE-MS II) (Poster Session 2, P1181 September 16; 3:30 – 5:00 p.m. BST)

Alemtuzumab Reduces the Rate of Brain Volume Loss in RRMS Patients Who Switched From SC IFNB-1a to Alemtuzumab (4-Year Follow-Up of the CARE-MS I and II Studies) (Poster Session 2, P1177 September 16; 3:30 – 5:00 p.m. BST)

Alemtuzumab Suppresses MRI Disease Activity Over 6 Years in Patients With Active Relapsing-Remitting Multiple Sclerosis and an Inadequate Response to Prior Therapy (CARE-MS II) (Poster Session 2, P1221 September 16; 3:30 – 5:00 p.m. BST)

A Network Meta-Analysis Comparing Alemtuzumab to Natalizumab in Patients With Relapsing-Remitting Multiple Sclerosis With Rapidly Evolving Severe Disease (ePoster EP1479)

Switching From Natalizumab to Alemtuzumab in Patients with RRMS: Real-World Experience (ePoster EP1498)

**Aubagio:**

- Stable Disability and Patient-Reported Performance Outcomes Over 48 Weeks of Teriflunomide Treatment: Results From the Phase 4 Teri-PRO Study (Poster Session 1, P646 September 15; 3:45 – 5:00 p.m. BST)
- Impact of Teriflunomide Treatment on Real-World Quality of Life in the Phase 4 Teri-PRO Study (Poster Session 1, P647 September 15; 3:45 – 5:00 p.m. BST)
- Teriflunomide Real-World Safety Profile: Results of the Phase 4 Teri-PRO Study (Poster Session 1, P648 September 15; 3:45 – 5:00 p.m. BST)
- Teriflunomide Impacts Primary Microglia and Astrocyte Functions In Vitro (Poster Session 1, P670 September 15; 3:45 – 5:00 p.m. BST)
- Outcomes of the TOPIC Extension Study of Teriflunomide in Patients With Early Multiple Sclerosis: Up to 7 Years of Clinical Results (Poster Session 1, P690 September 15; 3:45 – 5:00 p.m. BST)
- Benefit of Long-Term Treatment with Teriflunomide on Disability Outcomes: Results From TEMSO and TOWER (Poster Session 1, P691 September 15; 3:45 – 5:00 p.m. BST)
- Outcomes of the TEMSO Extension Study of Teriflunomide: 10.5 years of Clinical Results (Poster Session 1, P692 September 15; 3:45 – 5:00 p.m. BST)
- Effect of Teriflunomide on Relapse and Disability Worsening: A Post-Hoc Analysis of the TOWER Study With 2 years of Treatment (Poster Session 1, P731 September 15; 3:45 – 5:00 p.m. BST)
- Brain Volume Loss Correlates With Long-Term Disability Worsening in Patients With MS: SIENA Analysis of TEMSO MRI Data (Poster Session 1, P733 September 15; 3:45 – 5:00 p.m. BST)
- Teriflunomide is Effective in Reducing Brain Volume Loss in Previously Treated Patients: a Subgroup Analysis of TEMSO SIENA Data (Poster Session 1, P734 September 15; 3:45 – 5:00 p.m. BST)
- Utilizing Brain Volume Loss as an Additional Predictor of Long-Term Treatment Outcomes: Analysis of TEMSO MRI SIENA Data (Poster Session 1, P736 September 15; 3:45 – 5:00 p.m. BST)
- Measuring Treatment Satisfaction in Patients With RMS in the Real World: is the TSQM Fit For Purpose? An Evaluation Using Teri-PRO Study Data (Poster Session 1, P351 September 15; 3:45 – 5:00 p.m. BST)
- Treatment Preferences Related to Route of Administration in Patients with MS: Results from US and EU5 (ePoster EP1547)
- Real-World Healthcare Resource Utilization and Treatment Switching Patterns in Multiple Sclerosis Patients in a Large US Health Plan (ePoster EP1546)
- Nonclinical Data Demonstrate High Sensitivity of Rats Versus Humans to Embryo Foetal Toxicity When Exposed to Teriflunomide (ePoster EP1420)
- Improvements in Patient-Reported Treatment Satisfaction With Teriflunomide: Results From the Phase 4 Worldwide Teri-PRO Study (ePoster EP1484)
- Association of MS Disease Duration, Disability Worsening and Brain Volume Loss: SIENA Analysis of TEMSO MRI Data (ePoster EP1536)

**About Lemtrada (alemtuzumab)**

Lemtrada is approved in more than 50 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 9,200 patients have been treated with Lemtrada commercially worldwide.

The precise mechanism by which alemtuzumab exerts its therapeutic effects in MS is unknown. 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. Lemtrada 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.

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.

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

About Aubagio® (teriflunomide)
Aubagio® is approved in more than 60 countries, with additional marketing applications under review by regulatory authorities globally. More than 60,000 people have been treated with Aubagio commercially 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-
commercial success of therapeutic alternatives, Sanofi’s the absence of guarantee that the product including post marketing, decisions by regulatory authorities, such as expressed in, or implied or “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 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, Sanofi’s ability to benefit from external growth opportunities and/or obtain

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

Please see full U.S. 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 is organized into five global business units: Diabetes and Cardiovascular, General Medicines and Emerging Markets, Sanofi Genzyme, Sanofi Pasteur and Merial.

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

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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, estimates and 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, Sanofi’s ability to benefit from external growth opportunities and/or obtain
regulatory clearances, 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, 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:
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