Relapsing Remitting MS Patients Who Received Lemtrada® (alemtuzumab) Reported Improvements in Treatment Satisfaction and Health-Related Quality of Life in Clinical Studies

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Patients with relapsing remitting multiple sclerosis (RRMS) who received Sanofi's Lemtrada® (alemtuzumab) experienced improvements in treatment satisfaction and health-related quality of life, according to investigational data from two clinical studies. These results will be presented this week during the 71st annual meeting of the American Academy of Neurology (AAN) in Philadelphia, PA.

PRO-ACT Study
PRO-ACT is an ongoing, two-year, real-world study evaluating patient-reported treatment satisfaction among RRMS patients who switched to Lemtrada from another disease-modifying therapy, as measured by the Treatment Satisfaction Questionnaire for Medication (TSQM). The TSQM includes four domains: global satisfaction, effectiveness, side effects, and convenience; these are rated on a scale of 0 to 100, with higher scores indicating greater satisfaction.

In an interim analysis of the PRO-ACT study, patients who had completed TSQM assessments at baseline and 12 months after starting Lemtrada reported improvements in global satisfaction (primary endpoint) and effectiveness; the side effects score decreased and the convenience score was stable.

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<tr>
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<th>Median Baseline Score</th>
<th>Median Month 12 Score</th>
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<tbody>
<tr>
<td></td>
<td>(number of patients)</td>
<td>(number of patients)</td>
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<tr>
<td>Global Satisfaction</td>
<td>50 (n=181)</td>
<td>64 (n=83)</td>
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<tr>
<td>Effectiveness</td>
<td>50 (n=178)</td>
<td>61 (n=84)</td>
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<tr>
<td>Side Effects</td>
<td>100 (n=179)</td>
<td>88 (n=84)</td>
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<tr>
<td>Convenience</td>
<td>67 (n=181)</td>
<td>67 (n=84)</td>
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The most common prior disease-modifying therapy before switching to Lemtrada was natalizumab (37 percent), followed by oral therapies fingolimod, dimethyl fumarate and teriflunomide (14, 13 and 12 percent, respectively), interferons-beta (11 percent) and glatiramer acetate (8 percent). The most frequent reason for switching was lack of efficacy (75 percent). These percentages are based on 201 patients enrolled in PRO-ACT as of June 2018.

PROMIS Study
PROMIS is an ongoing, one-year, real-world study evaluating patient-reported health-related quality of life, function and degree of disability in RRMS patients treated with Lemtrada.

It utilizes three patient-reported outcomes questionnaires: the Multiple Sclerosis Impact Scale (MSIS)-29, which evaluates health-related quality of life (the specific physical and psychological impact of MS); and the Multiple Sclerosis Performance Scale (MSPS) and the Patient-Determined Disease Steps (PDDS), both of which evaluate functional health (MS-associated disability). Higher scores indicate greater disability in functional health (MSPS and PDDS) or worse health-related quality of life (MSIS-29).

In an interim analysis that included 171 patients at baseline, over eight months after initiation with Lemtrada, patients reported significant and clinically meaningful improvements in health-related quality of life. Patients also reported statistically significant improvements in functional health.

- Mean MSIS-29 scores improved at month 8 after Lemtrada initiation (n=134) vs. baseline (physical impact score, 43.0 vs. 53.1; psychological impact score, 36.8 vs. 49.4; both p<0.0001), reaching the established threshold for a clinically important change (≥ 7.5-point reduction from baseline for physical impact score).
- The mean total MSPS score was 16.6 at baseline and improved to 14.9 at month 8 after initiation with Lemtrada in 134 patients (p<0.05). The mean PDDS score was 3.5 at baseline and improved to 3.1 at month 6 in 143 patients (p<0.05).

“Patient-reported outcomes are increasingly being used in clinical practice to provide insight into the patient’s perspective of relapsing MS and treatment,” said Sibyl Wray, M.D., Director of the Hope Neurology MS Center in Knoxville, TN. “The interim results being reported at AAN from the PRO-ACT and PROMIS studies are encouraging, as they show that Lemtrada-treated patients experienced improvements in treatment satisfaction and health-related quality of life.”

In clinical trials, serious side effects associated with Lemtrada included infusion reactions, stroke and cervicocephalic arterial
dissection, autoimmune disorders (such as thyroid disease, autoimmune cytopenias, and nephropathies), autoimmune hepatitis, infections, acute acalculous cholecystitis, and pneumonitis. Lemtrada may cause an increased risk of malignancies. Risk management programs incorporating education and monitoring help support early detection and management of key identified and potential risks.

The most common side effects of Lemtrada are rash, headache, pyrexia, nasopharyngitis, nausea, urinary tract infection, fatigue, insomnia, upper respiratory tract infection, herpes viral infection, urticaria, pruritus, thyroid gland disorders, fungal infection, arthralgia, pain in extremity, back pain, diarrhea, sinusitis, oropharyngeal pain, paresthesia, dizziness, abdominal pain, flushing, and vomiting. (See Important Safety Information below.)

About Lemtrada® (alemtuzumab)
Lemtrada is approved in more than 70 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 >11,000 patient-years of follow-up. More than 24,0001 patients have been treated with Lemtrada commercially worldwide.

Sanofi Genzyme, the specialty care business of Sanofi, 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.

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 thrombocytopenic purpura (ITP), a condition of reduced platelet counts in your blood that can cause severe bleeding that 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; coughing up blood; 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 if not treated, can 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: swelling of your legs or feet; blood in the urine (red or tea-colored urine); decrease in urine; fatigue; 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
- trouble breathing
- weakness
- fast, slow, or irregular heartbeat
- chest pain
- 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 if they happen.

Strokes and tears in your arteries that supply blood to your brain (carotid and vertebral arteries): Some people have had serious and sometimes deadly strokes and tears in their carotid or vertebral arteries within 3 days of receiving LEMTRADA. Get help right away if you have any of the following symptoms that may be signs of stroke or tears in your carotid or vertebral arteries:

- drooping of parts of your face
• weakness on one side
• sudden severe headache
• difficulty with speech
• neck pain

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

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.**

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

**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 loss
• fast heartbeat
• eye swelling
• nervousness
• unexplained weight gain
• feeling cold
• worsening tiredness
• constipation

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

**Inflammation of the liver:** Call your healthcare provider right away if you have symptoms such as unexplained nausea, stomach pain, tiredness, loss of appetite, yellowing of skin or whites of eyes, or bleeding or bruising more easily than normal.

**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:

• **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 are heated well.

• **Herpes viral infections.** Some people taking LEMTRADA have an increased chance of getting herpes viral infections. Take 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.

**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
- cough
- wheezing
- chest pain or tightness
- coughing up blood

**Before receiving LEMTRADA, tell your healthcare provider if you:**

- have bleeding, thyroid, or kidney problems
- have a recent history of infection
- are taking a medicine called Campath® (alemtuzumab)
- 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.

**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 negative side effects of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088

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.sanogenzyme.com.

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