Treatment Effects Maintained Over Five Years in Patients with Relapsing Remitting Multiple Sclerosis who Received Sanofi Genzyme’s Lemtrada® (alemtuzumab) in Extension Study After Switching from Interferon Beta-1a

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- At five years in the extension of two Phase III studies, 71 and 61 percent of patients received no additional treatment after the initial two courses of Lemtrada -

- Consistent effects seen across relapse, disability, brain atrophy and MRI disease activity -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Sanofi Genzyme, the specialty care global business unit of Sanofi, announced today that relapsing remitting multiple sclerosis (RRMS) patients who received Lemtrada® (alemtuzumab) after switching from interferon beta-1a at the time of entry into the extension of two Phase III trials experienced effects of treatment on disease activity that were maintained over five years. These investigational data are being presented during the 7th Joint Meeting of the European and Americas Committees for Research and Treatment in Multiple Sclerosis (ECTRIMS-ACTRIMS).

The Phase III trials of Lemtrada were randomized, open-label, rater-blinded, two-year pivotal studies comparing treatment with Lemtrada to high-dose subcutaneous interferon beta-1a (IFNB-1a) in patients with RRMS who had active disease and were either new to treatment (CARE-MS I) or who had an inadequate response to another therapy (CARE-MS II).

Approximately 80 percent of patients from both pivotal studies who were treated with IFNB-1a elected to discontinue that treatment, enter the extension study, and initiate therapy with Lemtrada (CARE-MS I, n=139; CARE-MS II, n=143). They received their first course of Lemtrada upon entering the extension and their second course 12 months later. The following data are results for these patients through year five of the extension.

- After receiving the initial two courses of Lemtrada, 71 percent (n=98) and 61 percent (n=87) of IFNB-1a-treated patients from CARE-MS I and II, respectively, received no further treatment through year five of the extension; they were eligible to receive either retreatment with Lemtrada or treatment with any other MS disease-modifying therapy.
- Annualized relapse rates, which were 0.39 (CARE-MS I) and 0.52 (CARE-MS II) during IFNB-1a treatment, significantly declined to 0.11 and 0.15, respectively, over two years after patients initiated Lemtrada (both p<0.0001), and remained low through year five (0.09 and 0.18 in year five).
- Through year five of the extension study after initiating Lemtrada, 75 percent and 74 percent of IFNB-1a-treated patients from CARE-MS I and II, respectively, did not experience disability worsening. This was defined as ≥ a 1-point increase in Expanded Disability Status Scale (EDSS) score (or ≥ 1.5 points if baseline EDSS=0), confirmed over six months.
- Through year five of the extension study after initiating Lemtrada, 28 percent and 23 percent of IFNB-1a-treated patients from CARE-MS I and II, respectively, experienced disability improvement. This was defined as ≥ a 1-point decrease in EDSS score, confirmed over six months; it was assessed only in patients who had baseline EDSS scores ≥ 2.0.
- Yearly brain volume loss (atrophy), as measured by brain parenchymal fraction on magnetic resonance imaging (MRI), was -0.50 and -0.33 in the patients’ second year of IFNB-1a treatment in CARE-MS I and II, respectively. This slowed to -0.07 and 0.02 in year one of the extension study after initiating Lemtrada, and remained low through year five (-0.13 and -0.08 in year five).
- The percentage of patients who were free of MRI disease activity significantly increased from 59 percent and 47 percent in their second year of IFNB-1a treatment (in CARE-MS I and II, respectively) to 82 percent and 81 percent (both p<0.001) in year two of the extension study after initiating Lemtrada. The percentage of patients who were free of MRI disease activity remained high in year five of the extension (67 percent for both CARE-MS I and II).
The yearly incidence of most adverse events, including infections, was reduced or similar in year five compared with years one through four post Lemtrada treatment. The incidence of thyroid adverse events was highest in year three (CARE-MS I, 11.6 percent; CARE-MS II, 12.4 percent) and declined thereafter.

“The extension study data being presented at ECTRIMS illustrate that most patients who switched from IFNB-1a to Lemtrada experienced reduced disease activity,” said Aaron L. Boster, M.D., Systems Medical Chief, Neuroimmunology for OhioHealth in Columbus, Ohio. “The improvements observed across relapse, disability, brain atrophy and MRI activity were maintained over five years, even though approximately two-thirds of patients received no additional treatment following the initial two courses of Lemtrada.”

In clinical trials, serious side effects associated with Lemtrada included infusion reactions, autoimmune disorders (such as thyroid disease, autoimmune cytopenias, and nephropathies), 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 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 16,000® 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

LEMTTRA 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

LEMTTRA 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
- 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 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
- 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.**

**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
- eye swelling
- nervousness
- fast heartbeat
- 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

**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 if not treated, can lead to 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
- cough
- wheezing
- chest pain or tightness
- coughing up blood

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 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, Empowering Life

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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1 Company data on file

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 marketing and other potential of the product, or regarding potential future revenues from the product. 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, unexpected regulatory actions or delays, or government regulation generally, that could affect the availability or commercial potential of the product, the absence of guarantee that the product will be commercially successful, the uncertainties inherent in research and development, including future clinical data and analysis of existing clinical data relating to the product, including post marketing, unexpected safety, quality or manufacturing issues, competition in general, risks associated with intellectual property and any related future litigation and the ultimate outcome of such litigation, 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.

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