Treatment Effects Maintained over Seven Years in Patients with Relapsing Remitting Multiple Sclerosis Who Received Lemtrada® (alemtuzumab) in Clinical Trials

Release Date:  
Monday, April 23, 2018 9:20 am EDT

Terms:

Dateline City:  
CAMBRIDGE, Mass.

* At seven years in the extension of two Phase III pivotal studies, 59 and 47 percent of patients received no additional treatment after the initial two courses of Lemtrada

* Consistent effects seen across relapse, disability, brain volume loss and MRI lesion activity

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Patients with relapsing remitting multiple sclerosis (RRMS) who received Sanofi Genzyme’s Lemtrada® (alemtuzumab) experienced effects of treatment on disease activity that were maintained over seven years, according to data from the extension of two pivotal studies. These results will be presented this week during the 70th annual meeting of the American Academy of Neurology (AAN) in Los Angeles, CA.

Among RRMS patients treated with Lemtrada in the two-year CARE-MS pivotal studies, 80 percent (n=299) from CARE-MS I and 73 percent (n=317) from CARE-MS II completed long-term follow-up through year seven. Key findings include:

- After the initial two courses of Lemtrada, which patients received upon study entry and 12 months later, 59 percent (n=206) of Lemtrada patients from CARE-MS I and 47 percent (n=185) from CARE-MS II received no further treatment during the following six years. Patients were eligible to receive either retreatment with Lemtrada or treatment with another MS disease-modifying therapy.
- The annualized relapse rates observed in patients who received Lemtrada in CARE-MS I (0.18) and CARE-MS II (0.26) remained low throughout the extension (0.13 and 0.14 at year seven.)
- At year seven, 74 percent and 69 percent of Lemtrada-treated patients from CARE-MS I and CARE-MS II, respectively, did not experience confirmed disability worsening\(^1\); 37 percent and 44 percent, respectively, experienced confirmed disability improvement\(^2\).
- Through year seven, patients who received Lemtrada in CARE-MS I and II experienced a slowing of brain volume loss\(^3\). In years three through seven, the median yearly brain volume loss was -0.20 percent or less, which was lower than what was observed in the Lemtrada-treated patients during the pivotal studies (CARE-MS I: -0.59 percent in year one; -0.25 percent in year two; CARE-MS II: -0.48 percent in year one; -0.22 percent in year two).
- In each year through year seven, most patients had no evidence of magnetic resonance imaging (MRI) disease activity\(^4\) (CARE-MS I: 66 – 77 percent; CARE-MS II: 67 – 76 percent).
- Through year seven, the yearly incidence of most adverse events during the extension was comparable or reduced compared with the pivotal studies. The frequency of thyroid adverse events was highest in year three (CARE-MS I: 15 percent; CARE-MS II: 17 percent) and generally declined thereafter. There were three deaths in year seven, none of which was considered related to Lemtrada by the study investigators.

“The extension study data being presented at AAN illustrate that more than two-thirds of patients did not experience confirmed disability worsening at year seven after initiating treatment with Lemtrada,” said Barry Singer, M.D., Director of The MS Center for Innovations in Care at Missouri Baptist Medical Center, St. Louis, MO. “In addition, consistent effects were maintained over time across relapses and MRI outcomes including brain volume loss, even though the majority of patients did not receive any additional treatment over the prior six years.”

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 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).

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 19,000 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
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.

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.
Endnotes

(1) Confirmed disability worsening 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.

(2) Confirmed disability improvement 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.

(3) Brain volume loss was measured by brain parenchymal fraction on MRI.

(4) MRI disease activity was defined as no new gadolinium-enhancing T1 lesions and no new or enlarging T2 lesions.

(5) 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.sanofigenzyme.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
Tel.: +1-617-685-5068
erin.pascal@sanofi.com

Sanofi Media Relations Contact
Ashleigh Koss
Tel.: +1-908-981-8745
Mobile: +1-908-205-2572