Genzyme to Present New Long-Term Data on Aubagio® (teriflunomide) and Lemtrada® (alemtuzumab) at AAN

Release Date: Monday, April 13, 2015 9:00 am EDT

Terms:

Dateline City: CAMBRIDGE, Mass.

- 30 Presentations Planned On Marketed Products and New Data from Company’s MS Pipeline -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Genzyme, a Sanofi company, announced today that new longer-term data on its relapsing multiple sclerosis treatments, Aubagio® (teriflunomide) and Lemtrada® (alemtuzumab), will be featured during the 67th annual meeting of the American Academy of Neurology (AAN) being held in Washington, D.C. April 18-25. The company will present 30 platform and poster presentations from its MS franchise, including 19 on Lemtrada, 10 on Aubagio and one pipeline presentation. Key data being presented at AAN include:

- 12-Year Clinical Efficacy and Safety Data for Teriflunomide: Results from a Phase 2 Extension Study (Poster Session – P7.223; April 23; 2:00 – 6:30 p.m. EDT)
- Assessing Comparative Outcomes from Teriflunomide and Dimethyl Fumarate Studies in Relapsing MS: Use of “Number Needed to Treat” Analysis (Poster Session – P3.245; April 21; 2:00 – 6:30 p.m. EDT)
- Durable Effect of Alemtuzumab on MRI Activity in Treatment-Naive Active Relapsing-Remitting Multiple Sclerosis Patients: 4-Year Follow-up of CARE-MS I (Poster Session – P7.246; April 23; 2:00 – 6:30 p.m. EDT)
- Durable Effect of Alemtuzumab on MRI Outcomes in Patients With Relapsing-Remitting Multiple Sclerosis Who Relapsed on Prior Therapy: 4-Year Follow-up of CARE-MS II (Poster Session – P7.249; April 23; 2:00 – 6:30 p.m. EDT)
- Alemtuzumab Slows Brain Volume Loss Over 4 Years Despite Most Relapsing-Remitting Multiple Sclerosis Patients Not Receiving Treatment for 3 Years (Poster Session – P7.263; April 23; 2:00 – 6:30 p.m. EDT)
- Characterization of a Next Generation Anti-CD52 Antibody (Platform Session – S20.006; April 22; 3:15 p.m. EDT)

Genzyme’s MS R&D pipeline is focused on investigational treatments to help address unmet needs for relapsing and progressive forms of MS through research in selective immunomodulation, neuroprotection and remyelination. The investigational anti-CD52 antibody GZ402668 is currently in a Phase 1 trial in MS patients, including intravenous and subcutaneous administration. Genzyme is also developing vatelizumab, an investigational anti-VLA-2 humanized monoclonal antibody currently in a Phase 2 trial for relapsing forms of MS.

“The data we’re presenting at AAN this year help address important scientific questions about Aubagio and Lemtrada over the long-term, and in comparison with other therapies,” said Bill Sibold, Head of Genzyme’s Multiple Sclerosis business. “We’re also very excited to share some additional findings on the next generation of potential Genzyme MS therapies. Our presence at AAN demonstrates our long-term commitment to the MS community, and our continued focus to address unmet needs for people living with MS.”

The list of Genzyme’s additional presentations at AAN is as follows, along with information about company-sponsored activities.

Aubagio:

- Teriflunomide Shows Consistent Clinical Efficacy on Severe Relapses across Two Phase 3 Trials in Patients with Relapsing forms of Multiple Sclerosis, TEMSO and TOWER (Poster Session – P7.212; April 23; 2:00 – 6:30 p.m. EDT)
- Teriflunomide Significantly Increased Time to First Relapse in TEMSO, TOWER and TOPIC (Poster Session – P7.279; April 23; 2:00 – 6:30 p.m. EDT)
- Positive MRI Outcomes in Patients with Early Multiple Sclerosis Treated with Teriflunomide: Subgroup Analyses from the TOPIC Phase 3 Study (Poster Session – P7.253; April 23; 2:00 – 6:30 p.m. EDT)
- The Clinical Course of Hair Thinning Associated with Teriflunomide: Case Series of Patients Who Participated in a Hair Photography Project (Poster Session – eP7.016; April 23; 2:00 – 6:30 p.m. EDT)
- How Satisfied with Their Treatment Are Patients with MS? Psychometric Evaluation of the Treatment Satisfaction Questionnaire for Medication (TSQM) (Poster Session – P3.236; April 21; 2:00 – 6:30 p.m. EDT)
- Safety and Efficacy of Teriflunomide in Patients Switching from Subcutaneous Interferon Beta-1a (Poster Session –
Teriflunomide is the principal active metabolite of leflunomide, which is indicated in the U.S. for the treatment of rheumatoid arthritis. Severe liver injury including fatal liver failure has been reported in patients treated with leflunomide. ALT should be monitored monthly for at least 6 months in patients who start treatment with Aubagio.

**Aubagio® (teriflunomide) U.S. Indication and Usage**

Aubagio is a once-daily, oral therapy indicated in the U.S. for the treatment of adult patients with relapsing forms of multiple sclerosis. The recommended dose of Aubagio is 7 mg or 14 mg orally once-daily.

**Important Safety Information About Aubagio for U.S. Patients**

The Aubagio label includes the risk of hepatotoxicity and, teratogenicity (based on animal data). In the United States, this information can be found in the boxed warning.

In MS clinical studies with Aubagio, the incidence of serious adverse events were similar among Aubagio and placebo-treated patients. Serious events may include decreased white blood cell count, peripheral neuropathy, hyperkalemia, skin reactions and increased blood pressure. The most common adverse events associated with Aubagio in MS patients included increased ALT levels, alopecia, diarrhea, influenza, nausea and paresthesia.

Teriflunomide is the principal active metabolite of leflunomide, which is indicated in the U.S. for the treatment of rheumatoid arthritis. Severe liver injury including fatal liver failure has been reported in patients treated with leflunomide. ALT should be monitored monthly for at least 6 months in patients who start treatment with Aubagio.
Aubagio is contraindicated in patients with severe hepatic impairment, pregnant women and women of childbearing potential who are not using reliable contraception and in patients who are taking leflunomide. Aubagio is not recommended for breast feeding women, patients with immunodeficiency states, patients with significantly impaired bone marrow function or significant anemia, leucopenia, neutropenia or thrombocytopenia, patients with severe active infection until resolution, patients with severe renal impairment undergoing dialysis and patients with hypoproteinaemia.

For full prescribing information and more information about Aubagio for U.S. patients, please visit: http://products.sanofi.us/aubagio/aubagio.pdf.

About Aubagio® (teriflunomide)

Aubagio is approved in more than 50 countries, with additional marketing applications under review by regulatory authorities globally.

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. Some patients in extension trials have been treated for up to 10 years.

Lemtrada® (alemtuzumab) U.S. Indication and Usage

Lemtrada is indicated in the United States for the treatment of patients with relapsing forms of multiple sclerosis (MS). Because of its safety profile, the use of Lemtrada should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

Please click here for full U.S. Prescribing Information for Lemtrada, including boxed warning and contraindications.

Important Safety Information About Lemtrada for U.S. Patients

Serious and life-threatening autoimmune conditions such as immune thrombocytopenia (ITP) and anti-glomerular basement membrane disease can occur in patients receiving Lemtrada. Monitor or complete blood counts with differential, serum creatinine levels, and urinalysis with urine cell counts at periodic intervals in patients who receive Lemtrada. Lemtrada is associated with serious and life-threatening infusion reactions. Lemtrada can only be administered in certified healthcare settings that have on-site access to equipment and personnel trained to manage anaphylaxis and serious infusion reactions. Lemtrada may be associated with an increased risk of malignancy, including thyroid cancer, melanoma and lymphoproliferative disorders. The Lemtrada REMS Program, a comprehensive risk management program with frequent monitoring, is being implemented to help mitigate these serious risks.

In the U.S., the Lemtrada label includes a boxed warning noting a risk of serious, sometimes fatal autoimmune conditions, serious and life-threatening infusion reactions and also noting Lemtrada may cause an increased risk of malignancies including thyroid cancer, melanoma and lymphoproliferative disorders. Lemtrada is contraindicated in patients with Human Immunodeficiency Virus (HIV) infection.

About Lemtrada® (alemtuzumab)

Lemtrada is approved in more than 40 countries, with additional marketing applications under review. Lemtrada is supported by a comprehensive and extensive clinical development program that involved nearly 1,500 patients and 5,400 patient-years of follow-up.

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. Although the exact mechanism of action for alemtuzumab is not fully understood, it is presumed to deplete 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.

About Genzyme, a Sanofi Company

Genzyme has pioneered the development and delivery of transformative therapies for patients affected by rare and debilitating diseases for over 30 years. We accomplish our goals through world-class research and with the compassion and commitment of our employees. With a focus on rare diseases and multiple sclerosis, we are dedicated to making a positive impact on the lives of the patients and families we serve. That goal guides and inspires us every day. Genzyme’s portfolio of transformative therapies, which are marketed in countries around the world, represents groundbreaking and life-saving advances in medicine. As a Sanofi company, Genzyme benefits from the reach and resources of one of the world’s largest pharmaceutical companies, with a shared commitment to improving the lives of patients. Learn more at www.genzyme.com.

Genzyme®, Aubagio® and Lemtrada® are registered trademarks of Genzyme Corporation. All rights reserved.

About Sanofi

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients’ needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (Euronext: SAN) and in New York (NYSE: SNY).

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 policies 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, 2014. 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:
Genzyme Media Relations
Erin Pascal, +1 617-768-6864
erin.pascal@genzyme.com
or
Sanofi Investor Relations
Sébastien Martel, +33 (0) 1 53 77 45 45
ir@sanofi.com

Ticker Slug:
Ticker: SAN
Exchange: BOURSE
ISIN: FR0000120578
Ticker: SNY
Exchange: NYSE
ISIN: US80105N1054