Genzyme to Feature Multiple Sclerosis Pipeline and Present New Data on Aubagio and Lemtrada at ECTRIMS

Release Date: Monday, September 8, 2014 8:00 am EDT

Terms:
Dateline City: CAMBRIDGE, Mass.

- Genzyme Pursuing Innovative Approaches for Investigational Treatments Targeting Relapsing and Progressive Forms of MS –

- More Than 25 Oral and Poster Presentations Reinforce the Breadth and Depth of Genzyme’s MS Clinical Development Programs –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Genzyme, a Sanofi company (EURONEXT: SAN and NYSE: SNY), announced today that its multiple sclerosis pipeline, which includes a new generation of investigational treatments in early development, will be featured during the 30th Congress of the European Committee for Research and Treatment in Multiple Sclerosis (ECTRIMS) being held in Boston Sept. 10-13. The company will also present this week 26 oral and poster presentations from its MS franchise, including four-year results from the Lemtrada™ (alemtuzumab) extension study, 12-year MRI data for Aubagio® (teriflunomide), and data from the Aubagio TOPIC study, which was recently published in The Lancet Neurology.

In addition to its marketed therapies, Genzyme has an MS R&D pipeline focused on investigational treatments to address unmet needs for relapsing and progressive forms of MS through research in selective immunomodulation, neuroprotection and remyelination.

Key Genzyme MS programs and collaborations in clinical and preclinical development include:

- Vatelizumab – An investigational anti-VLA-2 humanized monoclonal antibody currently in a Phase II trial for relapsing forms of MS, in partnership with Glenmark Pharmaceuticals.

- GZ402668 – A next-generation investigational anti-CD52 humanized monoclonal antibody currently approaching Phase I clinical development.

- Discovery and research programs evaluating agents promoting remyelination, as well as agents targeted at central nervous system innate immune cells to provide neuroprotection.

- Collaborations with academic medical centers such as Brigham and Women’s Hospital to identify correlative biomarkers of disease progression, and with Cleveland Clinic to explore strategies to address neurodegeneration, a hallmark of progressive MS.

"Since FDA approval of once-daily oral Aubagio two years ago, Genzyme has continued to advance the understanding and treatment of MS by addressing important unmet medical needs for people living with the disease. Between clinical trials and commercial use in more than 40 countries, approximately 30,000 patients have now been treated with Aubagio," said Genzyme President and CEO David Meeker. "With Lemtrada, we have also made significant progress with approvals in more than 30 countries. With our differentiated marketed therapies and a varied pipeline focusing on innovative treatment approaches and underserved MS patients with progressive disease, we are uniquely positioned to bring long-term value to the MS community."

Presentations on Aubagio and Lemtrada at ECTRIMS are as follows, along with information about Genzyme-sponsored activities.

**Aubagio:**

- Long-term MRI outcomes from patients treated with teriflunomide: results from a phase 2 extension study. (Poster Session 1 – P079; Sept. 11; 3:30 – 5:00 p.m. EDT)

- Efficacy of teriflunomide in patients with early stage MS: analysis of the TOPIC study using 2010 McDonald diagnostic criteria. (Poster Session 1 – P095; Sept. 11; 3:30 – 5:00 p.m. EDT)

- MRI outcomes in patients with early multiple sclerosis treated with teriflunomide: subgroup analyses from the TOPIC phase 3 study. (Poster Session 1 – P040; Sept. 11; 3:30 – 5:00 p.m. EDT)

- Evaluating the effect of teriflunomide in subgroups defined by prior treatment: pooled analyses of the phase 3 TEMSO
and TOWER studies. (Poster Session 1 – P046; Sept. 11; 3:30 – 5:00 p.m. EDT)

- Teri-PRO: study design and US patients’ baseline characteristics. (Poster Session 1 – P078; Sept. 11; 3:30 – 5:00 p.m. EDT)
- Effect of teriflunomide on lymphocyte and neutrophil counts: pooled analyses from four placebo-controlled studies. (Poster Session 1 – P060; Sept. 11; 3:30 – 5:00 p.m. EDT)
- The efficacy of teriflunomide is evident before steady state plasma concentrations are reached. (Poster Session 1 – P058; Sept. 11; 3:30 – 5:00 p.m. EDT)
- Pooled safety analyses from the teriflunomide clinical development program. (Poster Session 1 – P097; Sept. 11; 3:30 – 5:00 p.m. EDT)
- Pregnancy outcomes for female patients and partners of male patients in the teriflunomide clinical development program. (Poster Session 1 – P097; Sept. 11; 3:30 – 5:00 p.m. EDT)
- Teriflunomide mechanism of action: linking preclinical evidence to clinical efficacy and safety. (Poster Session 2 – P959; Sept. 11; 3:30 – 5:00 p.m. EDT)

Lemtrada:

- Disease-free outcomes with alemtuzumab: 3-year follow-up of the CARE-MS studies. (Oral platform presentation – FC1.4; Sept. 12; 8:15 – 9:15 a.m. EDT)
- Alemtuzumab improves MRI outcomes in treatment-naive active relapsing-remitting multiple sclerosis patients: 3-year follow-up from CARE-MS I. (Oral platform presentation – FC2.2; Sept. 12; 8:15 – 9:15 a.m. EDT)
- Alemtuzumab improves MRI outcomes in relapsing-remitting multiple sclerosis patients who relapsed on prior therapy: 3-year follow-up of CARE-MS II. (Poster Session 1 – P103; Sept. 11; 3:30 – 5:00 p.m. EDT)
- Efficacy and safety of alemtuzumab in treatment-naive patients with relapsing-remitting MS: four-year follow-up of the CARE-MS I study. (Poster Session 1 – P090; Sept. 11; 3:30 – 5:00 p.m. EDT)
- Efficacy and safety of alemtuzumab in patients with relapsing-remitting MS who relapsed on prior therapy: four-year follow-up of the CARE-MS II study. (Poster Session 1 – P043; Sept. 11; 3:30 – 5:00 p.m. EDT)
- Improvement in MRI outcomes across subgroups with alemtuzumab versus interferon beta-1a in treatment-naive relapsing-remitting multiple sclerosis. (Poster Session 1 – P039; Sept. 11; 3:30 – 5:00 p.m. EDT)
- Alemtuzumab improves MRI outcomes regardless of subgroup versus interferon beta-1a in relapsing-remitting MS patients who relapsed on prior therapy. (Poster Session 1 – P075; Sept. 11; 3:30 – 5:00 p.m. EDT)
- Alemtuzumab reduces disease activity in treatment-naive patients with highly active relapsing-remitting multiple sclerosis. (Poster Session 1 – P088; Sept. 11; 3:30 – 5:00 p.m. EDT)
- Alemtuzumab improves quality of life in relapsing-remitting multiple sclerosis patients who relapsed on prior therapy: three-year follow-up of CARE-MS II. (Poster Session 1 – P044; Sept. 11; 3:30 – 5:00 p.m. EDT)
- Cost-effectiveness of alemtuzumab vs subcutaneous interferon beta-1a for the treatment of active relapsing-remitting multiple sclerosis: a payer perspective. (Poster Session 1 – P013; Sept. 11; 3:30 – 5:00 p.m. EDT)
- Greater cost savings associated with disability improvement in patients treated with alemtuzumab versus interferon beta-1a. (Poster Session 1 – P011; Sept. 11; 3:30 – 5:00 p.m. EDT)
- Anti-murine CD52 therapy provides anti-inflammatory and neuroprotective effects in EAE. (Poster Session 1 – P388; Sept. 11; 3:30 – 5:00 p.m. EDT)
- Defining clinical meaning of patient reported outcomes with disability assessment in multiple sclerosis: an analysis of the CARE-MS II study. (Poster Session 2 – P802; Sept. 12; 2:45 – 4:15 p.m. EDT)
- Pregnancy outcomes in the alemtuzumab MS clinical development program. (Poster Session 2 – P842; Sept. 12; 2:45 – 4:15 p.m. EDT)
- Management of infusion-associated reactions in alemtuzumab-treated relapsing-remitting multiple sclerosis patients. (Poster Session 2 – P880; Sept. 12; 2:45 – 4:15 p.m. EDT)
- Analysis of data from RRMS alemtuzumab-treated patients in the clinical program to evaluate incidence rates of malignancy. (Poster Session 2 – P868; Sept. 12; 2:45 – 4:15 p.m. EDT)

Abstracts are available on the ECTRIMS website.

Genzyme Symposium

“Emerging Trends in MS Pathophysiology: The Role of Mitochondria”

Date: Wednesday, Sept. 10 at 5:30 p.m.

Location: Veteran's Memorial Auditorium, 2nd floor, Hynes Convention Center

Genzyme Plenary

“Approaching the Cause of MS”

Date: Thursday, Sept. 11 at 9:00 a.m.

Location: Veteran’s Memorial Auditorium, 2nd and 3rd floors, Hynes Convention Center
**Genzyme Challenge Event**

Genzyme will engage the community in interactive events intended to bring to life some of the most common symptoms of MS – including vision impairment, cognitive challenges, and fatigue – and help participants better understand some of the challenges that people living with MS may face. For every person who participates in the experience, Genzyme will pledge volunteer hours that will be given back to the MS community. Visit the Prudential Center on Wednesday September 10 and Thursday September 11 to participate in the dynamic experiences.

**About Aubagio® (teriflunomide)**

Aubagio is approved in the United States, European Union, Australia, Argentina, Brazil, Canada, Chile, Columbia, Honduras, Mexico, New Zealand, Russia, South Korea, Switzerland, Turkey and Ukraine, 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.

**About Lemtrada™ (alemtuzumab)**

Lemtrada is approved in the European Union, Australia, Canada, Mexico, Brazil, Argentina, Chile and Guatemala. Lemtrada is currently not approved in the United States. The U.S. Food and Drug Administration (FDA) has accepted for review the company’s resubmission of its application seeking approval of Lemtrada, and Genzyme expects FDA action on the application in the fourth quarter. Marketing applications for Lemtrada are also under review in other countries. 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 selectively targets CD52, a protein abundant on T and B cells. Treatment with alemtuzumab results in the depletion of circulating T and B cells thought to be responsible for the damaging inflammatory process in MS. Alemtuzumab has minimal impact on other immune cells. The acute anti-inflammatory effect of alemtuzumab is immediately followed by the onset of a distinctive pattern of T and B cell repopulation that continues over time, rebalancing the immune system in a way that potentially reduces MS disease activity.

Genzyme holds the worldwide rights to alemtuzumab and has primary responsibility for its development and commercialization in multiple sclerosis. Bayer HealthCare holds the right to co-promote alemtuzumab in MS in the United States. Upon commercialization, Bayer will receive 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.

Genzyme® and Aubagio® are registered trademarks and Lemtrada™ is a trademark of Genzyme Corporation.

**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 labeling 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, 2013. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.