Genzyme’s Multiple Sclerosis Franchise Featured at AAN

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- Multiple Presentations Highlight Continuing Progress of AUBAGIO® and LEMTRADA™ Programs -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Genzyme, a Sanofi Company (EURONEXT: SAN and NYSE: SNY), announced today that data from its AUBAGIO® (teriflunomide) and LEMTRADA™ (alemtuzumab) multiple sclerosis clinical development programs will be presented during the 65th American Academy of Neurology (AAN) Annual Meeting to be held in San Diego, Calif., March 16-23.

"We are proud to present these results that offer important new insights into AUBAGIO and LEMTRADA," said Genzyme CEO and President, David Meeker, MD. "Our robust clinical development programs underscore our steadfast commitment to advancing our understanding of multiple sclerosis and its treatment, and to providing new hope for people living with this devastating disease."

Data from across the company’s clinical development programs to be presented at AAN during Pacific Time are as follows, along with details about the Genzyme Corporate Therapeutic Update and Brain Health Fair sponsorship.

Platform Presentations for AUBAGIO and LEMTRADA:

AUBAGIO:

- Pre-Defined Subgroups Analyses of TOWER, a Placebo-Controlled Phase 3 Trial of Teriflunomide in Patients with Relapsing Multiple Sclerosis (Platform Presentation Session 41 – S41.006; March 21; 1:30 p.m.)
- Teriflunomide Efficacy and Safety in Patients with Relapsing Multiple Sclerosis: Results From TOWER, a Second, Pivotal, Phase 3 Placebo-Controlled Study (Platform Presentation Session 1 – S01.004; March 19; 1:45 p.m.)
- Pregnancy Outcomes From the Teriflunomide Clinical Development Program: Retrospective Analysis of the Teriflunomide Clinical Trial Database (Platform Presentation Session 30 – S30.005; March 20; 3:00 p.m.)

LEMTRADA:

- Durable Efficacy of Alemtuzumab in Relapsing-Remitting Multiple Sclerosis Patients Who Participated in the CARE-MS Studies: Three Year Follow-Up (Platform Presentation Session 41 – S41.001; March 21; 12:00 p.m.)

Additional Presentations:

AUBAGIO:

Poster Presentations

- Immune Response to Seasonal Influenza Vaccination in Patients with Relapsing Multiple Sclerosis Treated with Teriflunomide: the TERIVA Study (Poster Session I – P01.169; March 18; 2:00 p.m.)
- Frequency of Infections During Treatment with Teriflunomide: Pooled Data From Three Placebo-Controlled Teriflunomide Studies (Poster Session I – P01.171; March 18; 2:00 p.m.)
- Teriflunomide Reduces Relapse-Related Sequelae, Hospitalizations and Corticosteroid Use: A Post-Hoc Analysis of the Phase 3 TOWER Study (Poster Session VII – P07.109; March 21; 2:00 p.m.)

LEMTRADA:

Poster Presentations

- Disability Improvement with Alemtuzumab vs. Interferon beta-1a in Relapsing-Remitting Multiple Sclerosis Patients Who Experienced Disease Activity While on Prior Therapy (CARE-MS II) (Poster Session VII - P07.120; March 21; 2:00 p.m.)
- Efficacy of Alemtuzumab vs IFNB-1a in Relapsing-Remitting Multiple Sclerosis Patients Who Experienced Disease Activity While on Prior Therapy (CARE-MS II): Subgroup Analysis by Previous Disease Modifying Therapy (DMT) Use (Poster Session VII – P07.111; March 21; 2:00 p.m.)
• Alemtuzumab Reduces MS Disease Activity in Active Relapsing-Remitting Multiple Sclerosis Patients Who Had Disease Activity on Prior Therapy (Poster Session VII – P07.093; March 21; 2:00 p.m.)

• Adverse Event Profile of Alemtuzumab Over Time in Active Relapsing-Remitting Multiple Sclerosis Patients Who Experienced Disease Activity While on Prior Therapy (CARE-MS II) (Poster Session I – P01.174; March 18; 2:00 p.m.)

• Detection, Incidence, and Management of Thyroid Autoimmunity in Comparison of Alemtuzumab and Rebif® in Multiple Sclerosis (CARE-MS I and II) (Poster Session I – P01.173; March 18; 2:00 p.m.)

• Comparison of Infection Risk with Alemtuzumab and SC IFNB-1a in Patients with Multiple Sclerosis Who Experienced Disease Activity While on Prior Therapy (CARE-MS II) (Poster Session I – P01.172; March 18; 2:00 p.m.)

• Anti-IFNB-1a Antibody Status Was Not a Factor Influencing Efficacy of Alemtuzumab vs IFNB-1a in Relapsing-Remitting Multiple Sclerosis Patients Who Experienced Disease Activity While on Prior Therapy (CARE-MS II) (Poster Session VII – P07.125; March 21; 2:00 p.m.)

• Immunogenicity of Alemtuzumab Treatment in Relapsing-Remitting Multiple Sclerosis (RRMS) Patients in the CARE-MS II Study (Poster Session VII – P07.101; March 21; 2:00 p.m.)

• Relapse Outcomes with Alemtuzumab vs IFNB-1a in Active Relapsing-Remitting Multiple Sclerosis Patients Who Experienced Disease Activity on Prior Therapy (CARE-MS II) (Poster Session VII – P07.098; March 21; 2:00 p.m.)

Abstracts are available on the AAN website.

Corporate Therapeutic Update
"Evolving Standards in MS Care"
When: Tuesday, March 19; 7:00 – 10:00 p.m.
Location: Hilton San Diego Bayfront Hotel (1 Park Boulevard, San Diego, CA)

Brain Health Fair
Genzyme is proud to serve as a platinum sponsor of this year’s Brain Health Fair, taking place on Saturday, March 16, 2013. The Brain Health Fair, presented by the American Brain Foundation, the foundation of the American Academy of Neurology, is a free event that is open to the public and designed to help connect patients, families and caregivers affected by neurologic disorders. Genzyme has invited Children’s Hope for Understanding Multiple Sclerosis (CHUMS) to host an interactive exhibit, where visitors can experience what it’s like to have MS through techniques that simulate common MS symptoms.

About LEMTRADA™ (alemuzumab)
Alemuzumab is a monoclonal antibody that selectively targets CD52, a protein abundant on T and B cells. Treatment with alemuzumab results in the depletion of circulating T and B cells thought to be responsible for the damaging inflammatory process in MS. Alemuzumab has minimal impact on other immune cells. The acute anti-inflammatory effect of alemuzumab 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 alemuzumab and has primary responsibility for its development and commercialization in multiple sclerosis. Bayer HealthCare retains an option to co-promote alemuzumab in multiple sclerosis. Bayer HealthCare has notified Genzyme of its intention to co-promote under this option. Upon regulatory approval and commercialization, Bayer would receive contingent payments based on sales revenue.

LEMTRADA™ is the proprietary name submitted to health authorities for the company’s investigational multiple sclerosis agent alemuzumab.

About AUBAGIO®
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).

Indications and Usage
AUBAGIO (teriflunomide) is a once-daily, oral treatment indicated for patients with relapsing forms of multiple sclerosis (MS). AUBAGIO 14 mg has shown significant efficacy across key measures of MS disease activity, including reducing relapses, slowing the progression of physical disability, and reducing the number of brain lesions as detected by MRI.

Important Safety Information About AUBAGIO
The AUBAGIO label includes a boxed warning citing the risk of hepatotoxicity and, teratogenicity (based on animal data). In MS clinical studies with AUBAGIO, the incidence of serious adverse events were similar among AUBAGIO and placebo-treated patients. 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. Leflunomide has an estimated 2.1 million patient years of exposure in rheumatoid arthritis globally since its launch.

AUBAGIO is contraindicated in pregnant women and women of childbearing potential who are not using reliable contraception. AUBAGIO is supported by a robust clinical program with more than 5,000 trial participants in 36 countries and is amongst the largest of any MS therapy. Some patients in extension trials have been treated for up to 10 years. The AUBAGIO approvals were based on efficacy data from the TEMSO (Teriflunomide Multiple Sclerosis Oral) trial.
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.

About Sanofi

Sanofi, a global and diversified 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).

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Rebif® is a registered trademark of EMD Serono, Inc. or affiliates.

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of EUR 17.2 billion (2011), is one of the world’s leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Medical Care and Pharmaceuticals divisions. Bayer HealthCare’s aim is to discover, develop, manufacture and market products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 55,700 employees (Dec 31, 2011) and is represented in more than 100 countries. Find more information at www.bayerhealthcare.com.

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 transformative 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, 2011. 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 Media Relations
Jean-Marc Podvin, +33 (0) 1 53 77 46 46
mr@sanofi.com
or
Sanofi Investor Relations
Sébastien Martel, +33 (0) 1 53 77 45 45
ir@sanofi.com
or
Sanofi Investor Relations
Kristen Galfetti, +1 908 981 5560
ir@sanofi.com
or
Genzyme Media Relations
Erin Walsh, +1 617 768 6881
erin.walsh@genzyme.com

Ticker Slug:
Ticker: SAN
Exchange: BOURSE
Ticker: SNY
Exchange: NYSE
ISIN:
US80105N2045