### Genzyme Announces Successful Phase III Results for Alemtuzumab (LEMTRADA(TM*)) in Multiple Sclerosis

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-Significant efficacy of alemtuzumab over interferon beta-1a (Rebif®) observed on both relapse and disability co-primary endpoints in treatment-experienced MS patients -

- Genzyme confirms Q1 2012 regulatory submission objective -

CAMBRIDGE, Mass. -- BUSINESS WIRE -- Genzyme, a Sanofi company (EURONEXT: SAN and NYSE: SNY), reports today that the Phase III CARE-MS II trial met both of its co-primary endpoints. Relapse rate and sustained accumulation (worsening) of disability (SAD) were significantly reduced in multiple sclerosis patients receiving alemtuzumab (LEMTRADA™) as compared with Rebif® (44 mcg subcutaneous interferon beta-1a). Results for both of these co-primary endpoints were highly statistically significant. CARE-MS II is the randomized Phase III clinical trial comparing the investigational drug alemtuzumab to interferon beta-1a in patients with relapsing-remitting multiple sclerosis (RRMS). Patients were required to have experienced a relapse while on a prior therapy to be eligible for CARE-MS II. Genzyme is developing alemtuzumab in MS in collaboration with Bayer HealthCare.

In this randomized trial involving 840 patients, a 49 percent reduction in relapse rate was observed in patients treated with alemtuzumab 12 mg compared to interferon beta-1a over two years of study (p<0.0001). Importantly, there was also a 42 percent reduction in the risk of sustained accumulation (worsening) of disability as measured by the Expanded Disability Status Scale (EDSS) (p=0.0084). Analysis of the full CARE-MS II data is ongoing and results will be presented at a forthcoming scientific meeting.

"CARE-MS II represents the culmination of many years of clinical and laboratory research aimed at demonstrating the potential for alemtuzumab as a highly effective treatment for MS and understanding mechanisms involved in the complex natural history of the disease," said Professor Alastair Compston, Chair of the Steering Committee overseeing the conduct of the study and head of the Department of Clinical Neurosciences at the University of Cambridge, United Kingdom. "Taken together, the Phase II and III clinical trial data illustrate the promise that alemtuzumab holds as a transformative treatment for people with relapsing MS."

The CARE-MS II trial compared treatment with alemtuzumab 12 mg given daily as an IV administration for 5 days, and then again for 3 days one year later, to treatment with interferon beta-1a 44 mcg administered by injection three times per week throughout the two years of study.

"The superior efficacy results for alemtuzumab, particularly the slowing of disability, are very promising since this was a head-to-head comparison trial with high dose subcutaneous interferon beta-1a," said Dr. Jeffrey Cohen, Professor of Medicine (Neurology), Cleveland Clinic Lerner College of Medicine; Director of Experimental Therapeutics, Mellen Center for MS Treatment and Research; and a member of the Steering Committee overseeing the conduct of the study. "These results suggest alemtuzumab's potential to offer patients with MS a new and effective treatment option."

The safety profile observed in the trial was consistent with previous alemtuzumab use in MS and adverse events continued to be manageable. The most common types of adverse events associated with alemtuzumab in the CARE-MS II study were infusion-associated reactions, the symptoms of which most commonly included headache, rash, nausea, hives, fever, itching, insomnia, and fatigue. Infections were common in both groups with a higher incidence in the alemtuzumab group. The most common infections in patients receiving alemtuzumab included upper respiratory and urinary tract infections, sinusitis and herpes simplex infections. Infections were predominantly mild to moderate in severity and there were no treatment-related life-threatening or fatal infections.

Approximately 16 percent of alemtuzumab-treated patients developed an autoimmune thyroid-related adverse event and approximately one percent developed immune thrombocytopenia during the two-year study period. These cases were detected early through a monitoring program and managed using conventional therapies. Patient monitoring for immune cytopenias and thyroid or renal disorders is incorporated in all Genzyme-sponsored trials of alemtuzumab for the investigational treatment of MS.

"We are very pleased with the results of the CARE-MS II study which are unprecedented," said David Meeker, M.D., President and Chief Executive Officer, Genzyme. "We believe that LEMTRADA™, with its impressive efficacy, novel dosing regimen and manageable safety profile, could make a very important contribution to the MS treatment landscape, where a significant
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