



# Genzyme's Lemtrada Resubmission Accepted for Review by FDA

- Agency action expected in Q4 2014 -

Paris, France - May 30, 2014 - Sanofi (EURONEXT: SAN and NYSE: SNY) and its subsidiary Genzyme announced today that the U.S. Food and Drug Administration (FDA) has accepted for review the company's resubmission of its supplemental Biologics License Application (sBLA) seeking approval of Lemtrada<sup>TM</sup> (alemtuzumab) for the treatment of relapsing forms of multiple sclerosis. A six-month review period has been assigned for the Lemtrada sBLA. Genzyme expects FDA action on the sBLA in the fourth quarter.

This resubmission is based on data from the same clinical studies included in the original sBLA, and provides supplemental analyses and additional information to specifically address issues previously noted by the FDA in its December 27, 2013 Complete Response Letter. The company resubmitted the sBLA earlier this month following constructive discussions with the agency.

## 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 <a href="https://www.genzyme.com">www.genzyme.com</a>.

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.

Genzyme<sup>®</sup> is a registered trademark and Lemtrada<sup>™</sup> 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 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, 2013. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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