



## FDA Grants Fast Track Designation to Genzyme's Investigational Substrate Reduction Therapy for the Treatment of Fabry Disease

**Paris - April 28, 2015** - [Sanofi](#) and its subsidiary [Genzyme](#) announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the development of GZ/SAR402671, a new investigational oral substrate reduction therapy for the treatment of Fabry disease.

FDA's Fast Track Drug Development Program is designed to facilitate frequent interactions with the FDA review team to expedite the clinical development and review of a New Drug Application (NDA) for medicines with the potential to treat serious or life-threatening conditions and address unmet medical needs for such diseases or conditions. It also provides the opportunity to submit sections of an NDA on a rolling basis before a sponsor submits the complete application. Genzyme is currently enrolling patients in its Phase 2a trial of GZ/SAR402671, and plans to enroll nine treatment-naïve male adult patients with Fabry disease in this international, multicenter study.

Fabry disease is a rare lysosomal storage disorder that results in abnormal tissue deposits of a particular fatty substance (called globotriaosylceramide, also referred to as GL-3 or Gb3) throughout the body. GZ/SAR402671 is a glucosylceramide synthase inhibitor that blocks the formation of glucosylceramide (GL-1), a key intermediate in the synthesis of GL-3.

*"Becoming a Fast Track Program is an important milestone and we appreciate this designation from FDA,"* said Genzyme's Acting Head of Rare Diseases, Richard Peters, M.D, Ph.D. *"We look forward to learning more about this small molecule, with the goal of providing more therapeutic options to the Fabry community as quickly as possible."*

### About Fabry Disease

Fabry disease is an inherited and progressive condition that is characterized by excessive accumulation of the lipid GL-3 in various organs and tissues. Early symptoms include significant pain, gastrointestinal disturbances, as well as other manifestations, and over time, patients may experience life threatening renal, cardiac and cerebrovascular events. As a result, patients with Fabry disease typically have a shortened life span. Fabry disease affects both males and females, with approximately 10,000 diagnosed patients in the world.

### 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](http://www.genzyme.com).

Genzyme® is a registered trademark of Genzyme Corporation. All rights reserved.

## 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 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.*

---

## Contacts:

### Sanofi Media Relations

Jack Cox  
Tel: +33 (0) 1 53 77 46 46  
Email: [mr@sanofi.com](mailto:mr@sanofi.com)

### Sanofi Investor Relations

Sébastien Martel  
Tel: +33 (0) 1 53 77 45 45  
Email: [ir@sanofi.com](mailto:ir@sanofi.com)

### Genzyme Media Relations

Lori Gorski  
Tel: +1 617 768 9344  
Email: [Lori.Gorski@genzyme.com](mailto:Lori.Gorski@genzyme.com)