

Sanofi  
Form 6-K  
June 01, 2012

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 6-K**

**REPORT OF FOREIGN PRIVATE ISSUER**  
**PURSUANT TO RULE 13a-16 OR 15d-16**  
**UNDER THE SECURITIES EXCHANGE ACT OF 1934**

For the month of June 2012

Commission File Number: 001-31368

**SANOFI**

(Translation of registrant's name into English)

54, rue La Boétie, 75008 Paris, FRANCE

(Address of principal executive offices)

## Edgar Filing: Sanofi - Form 6-K

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F  Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes  No

If  Yes  marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-

In June 2012, Sanofi issued the press release attached hereto as Exhibit 99.1 which is incorporated herein by reference.

**Exhibit List**

| Exhibit      | No. | Description   |
|--------------|-----|---|
| Exhibit 99.1 |     | Press release dated June 1, 2012: Genzyme Reports Positive Top-Line Results of TOWER, a Pivotal Phase III Trial for AUBAGIO <sup>TM*</sup> (teriflunomide) in Relapsing Multiple Sclerosis. |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: June 1, 2012

SANOFI

By /S/ John Felitti  
Name: John Felitti  
Title: Associate Vice President,

Corporate Law, Financial & Securities Law

**Exhibit Index**

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**PRESS RELEASE**

**Genzyme Reports Positive Top-Line Results of TOWER, a Pivotal Phase III Trial for AUBAGIO™\* (teriflunomide) in Relapsing Multiple Sclerosis**

*- Significantly reduced relapse rate and risk of sustained accumulation of disability in patients taking oral teriflunomide once daily -*

**Paris, France June 1, 2012** - Sanofi (EURONEXT: SAN and NYSE: SNY) and its subsidiary Genzyme announced today top-line results from the TOWER (Teriflunomide Oral in people With relapsing remitting multiple sclerosis) trial that assessed the efficacy and safety of once-daily, oral teriflunomide in patients with relapsing forms of multiple sclerosis (MS). In the study, patients receiving teriflunomide 14 mg had a statistically significant reduction in annualized relapse rate and risk of sustained accumulation of disability. Analysis of the full TOWER data is ongoing and results will be presented at a forthcoming scientific meeting.

This double-blind, multi-center trial enrolled 1,169 patients and compared once-daily treatment with either 7 mg or 14 mg oral teriflunomide against placebo. Results from the primary and secondary endpoints for the proposed 14 mg commercial dose include the following:

A 36.3 percent reduction in annualized relapse rate, the primary endpoint of the trial, was observed in patients who received teriflunomide compared to placebo ( $p < 0.0001$ )

A 31.5 percent reduction in the risk of 12-week sustained accumulation of disability, the main secondary endpoint, as measured by the Expanded Disability Status Scale (EDSS) was observed with teriflunomide compared to placebo ( $p = 0.0442$ )

*These encouraging results are consistent with the results on relapse rate and disability that were observed in the TEMSO study and highlight the promise of teriflunomide as a potential new treatment for many patients with relapsing MS,* said Genzyme President and CEO, David Meeker, M.D.

A 22.3 percent reduction in annualized relapse rate was observed in patients treated with teriflunomide 7 mg compared to placebo ( $p = 0.02$ ); there was no statistically significant difference observed between teriflunomide 7 mg and placebo for the risk of 12-week sustained accumulation of disability.

Patients who completed the trial were followed for a period between 48 and 173 weeks. The average duration of teriflunomide exposure in TOWER was 18 months. Adverse events observed in the trial were consistent with previous clinical trials with teriflunomide in MS. The most common types of adverse events reported more frequently in the teriflunomide arms were headache, ALT (Alanine transaminase) elevations, hair thinning, diarrhea, nausea and neutropenia. There was one death from a respiratory infection in the placebo arm and three deaths in the teriflunomide arms from a motor vehicle accident, suicide and sepsis.

Marketing applications for teriflunomide for the treatment of relapsing forms of MS are under review by the U.S. Food & Drug Administration (FDA), European Medicines Agency (EMA) and other regulatory authorities.

### **About Teriflunomide**

Teriflunomide, a once-daily, oral tablet, is an immunomodulator with a unique mechanism of action. Although the mechanism of action for teriflunomide is not fully understood, research supports that teriflunomide inhibits the proliferation of stimulated T and B lymphocytes in the periphery thought to be responsible for the damaging inflammatory process in MS, while generally maintaining normal immune function.

Teriflunomide is being studied in a large clinical program that is expected to include more than 5,000 trial participants in 36 countries. Five efficacy clinical trials are either completed or underway with teriflunomide, making the clinical program one of the largest of any MS agent under development. Teriflunomide has been studied in three multi-center Phase III studies in patients with relapsing MS, including the completed TEMSO and TENERE trials and the TOWER trial. Another Phase III study, TOPIC, is underway in early MS or CIS (clinically isolated syndrome). Teriflunomide is also being evaluated as an adjunctive therapy to interferon- $\beta$  in the Phase III TERACLES trial. With up to 10 years of continuous use in a Phase II extension, teriflunomide has the longest clinical experience of any investigational oral MS therapy.

\* AUBAGIO is the proprietary name submitted to health authorities for the company's investigational MS agent teriflunomide.

### **About the TOWER Trial**

TOWER is a Phase III, multi-center double-blind parallel-group placebo-controlled study of the efficacy and safety of teriflunomide in patients with relapsing MS followed by an open-label extension period.

The TOWER study included patients ages 18 to 55. The primary endpoint was the annualized relapse rate, defined as the number of confirmed relapses per patient-year. The key secondary endpoint was time to disability progression confirmed for a minimum of 12-weeks. Safety variables were defined as adverse events reported by the patients or noted by the investigator during the study period.

### **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).

### **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).

### **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, 2011. 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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