

# FDA Approves Sanofi's Nasacort<sup>®</sup> Allergy 24HR for Over-the-Counter Use

 Nasal Spray Treats Adults and Children with Seasonal and Year-Round Nasal Allergies -

Paris, France, October 11, 2013 - Sanofi (EURONEXT: SAN and NYSE: SNY) announced today that the U.S. Food and Drug Administration (FDA) approved Nasacort® Allergy 24HR nasal spray as an over-the-counter (OTC) treatment for seasonal and year-round nasal allergies in adults and children 2 years of age and older. Nasacort is the first and only medicine in its class to be available without a prescription and will be marketed by Sanofi's consumer healthcare division in the United States, Chattem, Inc.

"We believe there is significant value in making certain types of medicines, like Nasacort, directly available to consumers," said Anne Whitaker, President, North America Pharmaceuticals, Sanofi US. "Allergy sufferers will benefit from having an additional treatment option and it is a strong addition to our existing consumer healthcare portfolio."

Up to 60 million Americans suffer from seasonal and year-round nasal allergies annually. This can have a major disruption to the quality of life of both adults and children, interfering with sleep, outdoor activities, and for children their performance at school. Nasacort and nasal sprays in the same medication class are considered the most effective treatment for hay fever and other upper respiratory allergies

"By adding Nasacort to Chattem's growing consumer healthcare portfolio, we are expanding our successful OTC allergy offering that includes the Allegra family of products," said Zan Guerry, Chief Executive Officer. Chattem.

Nasacort is the only single active ingredient OTC medicine that relieves the full range of nasal allergy symptoms, including nasal congestion, for 24 hours with a single daily dose.

The FDA approval of Nasacort Allergy 24HR as an OTC treatment was based on data submitted from 13 placebo-controlled efficacy studies, and safety information from 43 clinical studies, as well as information from 16 years of post-marketing surveillance data for Nasacort AQ.

Chattem anticipates that Nasacort will be available in Spring 2014.



# **About Sanofi**

Sanofi, an integrated 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 is the holding company of a consolidated group of subsidiaries and operates in the United States as Sanofi US, also referred to as sanofi-aventis U.S. LLC. For more information on Sanofi US, please visit <a href="http://www.sanofi.us">http://www.sanofi.us</a> or call 1-800-981-2491.

# 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, 2012. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

#### **Contacts:**

# **Corporate Media Relations**

Jack Cox

Tel.: +33 1 53 77 94 74 jack.cox@sanofi.com

Lori Lukus Tel: 908-981-3876 Lori.Lukus@sanofi.com

### **Investor Relations**

Sébastien Martel Tel.: + 33 1 53 77 45 45 ir@sanofi.com

George Grofik Tel: 908-981-6031 George.Grofik@sanofi.com