



## **FDA Advisory Committee Recommends Approval of Sanofi's Nasacort® AQ Nasal Spray for Over-the-Counter Use**

***- Treats Seasonal and Year-round Nasal Allergy Symptoms in Adults and Children -***

**Paris, France, July 31, 2013** — Sanofi (EURONEXT: SAN and NYSE: SNY) announced today that the U.S. Food and Drug Administration's (FDA) Nonprescription Drugs Advisory Committee (NDAC) voted 10 to 6, with 2 abstentions, recommending approval of Nasacort AQ Nasal Spray (triamcinolone acetonide) for over-the-counter use in the U.S.

*"Today's positive NDAC vote was an important step forward in providing broader access to Nasacort AQ for nasal allergy sufferers,"* said Charles Hugh-Jones, MD, MRCP, Chief Medical Officer, Sanofi US. *"We appreciate the feedback from the Committee and look forward to working with FDA in completing its review."*

If approved by the FDA, Nasacort AQ would be first-in-class as an OTC medicine and marketed by Sanofi's consumer healthcare division, Chattem, Inc. The proposed OTC indication is temporary relief of nasal symptoms of hay fever or other upper respiratory allergies (allergic rhinitis) in adults and children 2 years of age and older.

*"The OTC availability of Nasacort would continue to build on Chattem's highly successful OTC launch of Allegra and further expand our consumer healthcare offering,"* said Anne Whitaker, President, North America Pharmaceuticals, Sanofi.

Among prescription and OTC allergy products, Nasacort AQ and other nasal sprays in the same medication class are considered the most effective treatment for hay fever and other upper respiratory allergies.

The NDAC panel's recommendation will be considered by the FDA in its review of the Supplemental New Drug Application (sNDA) for Nasacort AQ as an OTC treatment. The FDA's decision will also be 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.

### **Prescription Indication**

Nasacort AQ Nasal Spray is indicated for the treatment of the nasal symptoms of seasonal and perennial allergic rhinitis in adults and children 2 years of age and older.

### **Important Safety Information**

Nasacort AQ should not be administered to patients with history of hypersensitivity to triamcinolone acetonide or any of its ingredients. Use of Nasacort AQ Nasal spray may result in



local nasal effects such as epistaxis or, rarely, local candida infections or perforation of the nasal septum. Nasacort AQ Nasal spray should not be used until any nasal septal ulcers, surgery or trauma has healed. Corticosteroids, including Nasacort, may result in the development of cataracts or glaucoma. Patients with a history of these conditions or of increased intraocular pressure or vision change should be monitored. Corticosteroids can inhibit the immune system and can potentially worsen infections, including tuberculosis, chickenpox and measles. Hypercorticism or adrenal suppression can occur with high dosages of intranasal corticosteroids or at the regular doses in susceptible individuals. In such cases, Nasacort AQ Nasal spray should be discontinued slowly. Corticosteroids, including Nasacort AQ Nasal spray, may reduce growth velocity reduction in children when administered. A child's growth should be checked regularly while on Nasacort AQ Nasal spray and the lowest effective dose should be used. The most common adverse reactions across age groups include nose bleeds and flu like symptoms such as cough, sore or inflamed throat, and headache.

### **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 <http://www.sanofi.us> 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.*



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