



Sanofi's Xyzal[®] Allergy 24HR Approved for Over-the-Counter Use in the United States

Paris, France – February 1, 2017 – [Sanofi](#) announced today that the U.S. Food and Drug Administration (FDA) approved Xyzal[®] Allergy 24HR as an over-the-counter (OTC) treatment for the relief of symptoms associated with seasonal and year-round allergies. Specifically, two formulations of Xyzal are now approved for OTC use – 5 mg tablets for ages 6 years and older, as well as 0.5 mg/mL oral solution for ages 2 years and older. Xyzal is an oral antihistamine with a proven 24-hour effect.

“The FDA approval of Xyzal builds on our heritage of successful Rx-to-OTC switches, and adds another trusted option to our existing portfolio of OTC allergy medications,” said Robert Long, Head of North America Consumer Healthcare, Sanofi. *“We look forward to making it available to allergy sufferers across the country, as the latest product in our growing consumer healthcare business.”*

As many as 60 million Americans suffer from allergic rhinitis, which is also commonly known as hay fever.¹ Antihistamines are the most widely used medications to relieve hay fever symptoms.² Xyzal is an antihistamine that contains the active ingredient levocetirizine dihydrochloride, which has a well-established safety and efficacy profile. It offers 24-hour relief from runny nose, sneezing, itchy watery eyes and itching of the nose or throat, all in a single daily dose.

Sanofi Consumer Healthcare's existing allergy portfolio includes Allegra Allergy, which was approved for OTC use in 2011 and Nasacort Allergy 24HR, which was approved for OTC use in 2013. The company anticipates that Xyzal will be made available in Spring 2017.

About Sanofi

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi is organized into five global business units: Diabetes and Cardiovascular, General Medicines and Emerging Markets, Sanofi Genzyme, Sanofi Pasteur and Consumer Healthcare. 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

¹ American College of Allergy Asthma and Immunology (ACAAI). Allergic Rhinitis. Available online at <http://acaai.org/allergies/types/hay-fever-rhinitis>. Accessed November 11, 2016.

² American Academy of Allergy Asthma and Immunology (AAAAI). Antihistamines. Available online at <https://www.aaaai.org/conditions-and-treatments/conditions-dictionary/antihistamines>. Accessed November 11, 2016.



candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi's ability to benefit from external growth opportunities and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic conditions, the impact of cost containment initiatives 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, 2015. 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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