

# Sanofi Announces Auvi-Q<sup>™</sup>, the First and Only Voice-Guided Epinephrine Auto-Injector, is Now Available in the U.S.

-- Breakthrough device design talks patients and caregivers through the injection process --

**Paris, France – January 28, 2013 –** Sanofi (EURONEXT : SAN and NYSE : SNY) announced today that  $Auvi-Q^{TM}$  (epinephrine injection, USP) is now available in U.S. retail pharmacies nationwide with a prescription from a healthcare provider.

Auvi-Q is the first-and-only epinephrine auto-injector with audio and visual cues for the emergency treatment of life-threatening allergic reactions in people who are at risk for or have a history of anaphylaxis.<sup>1</sup> The size and shape of a credit card and the thickness of a smart phone, Auvi-Q is a breakthrough in epinephrine auto-injector device design that talks patients and caregivers step-by-step through the injection process.

"Patient feedback was a critical component to the development process for Auvi-Q," said Anne Whitaker, President, North America Pharmaceuticals, Sanofi. "The availability of Auvi-Q represents an important step forward in our continued innovation to meet the needs of people at risk for anaphylaxis and their caregivers."

Up to six million Americans may be at risk for anaphylaxis, although the precise incidence is unknown and likely underreported. While guidelines emphasize the importance of the life-saving role of epinephrine, two large surveys (n=600 and n=651) show that two-thirds of patients and caregivers do not carry their epinephrine auto-injectors as recommended, and nearly half worry that others will not know how to use their or their child's epinephrine auto-injector correctly during an emergency. Multiple studies have found an association between delay in epinephrine administration and death from anaphylaxis.

Life-threatening allergic reactions may occur as a result of exposure to allergens including foods such as peanuts, tree nuts, fish, shellfish, dairy, eggs, soy and wheat; insect stings; latex and medication, among other allergens and causes.

## **About Auvi-Q**

Auvi-Q provides users with audible and visual cues, including a five-second injection countdown and an alert light to signal when the injection is complete Auvi-Q also features an automatic retractable needle mechanism to help prevent accidental needle sticks.

Available in two different dosages, Auvi-Q 0.3mg delivers 0.3mg epinephrine injection and is intended for patients who weigh 66 pounds or more. Auvi-Q 0.15mg delivers 0.15mg epinephrine injection and is intended for patients who weigh 33 – 66 pounds. Auvi-Q has not been studied in patients weighing less than 33 pounds. Each Auvi-Q pack contains two devices - containing one dose of epinephrine each - and a non-active training device. Auvi-Q received U.S. Food and Drug Administration approval in August 2012.

Sanofi US licensed the North America commercialization rights to Auvi-Q from Intelliject, Inc., which has retained commercialization rights for the rest of the world. Eric and Evan Edwards, twin brothers who suffer from life-threatening allergies, and co-founders of Intelliject, Inc., developed Auvi-Q with a team of world class engineers and scientists. The development process incorporated real-world experiences and feedback from patients and caregivers.

Auvi-Q has been named an International CES Innovations 2013 Design and Engineering Awards Honoree. The prestigious Innovations Design and Engineering Awards are sponsored by the Consumer Electronics Association (CEA)<sup>®</sup>, the producer of the International CES and the world's largest consumer technology tradeshow. http://www.cesweb.org/Awards/CES-Innovations-Awards.aspx

### **About Anaphylaxis**

The signs and symptoms of anaphylaxis can vary from person to person and from one episode to the next. Some people may have hives/itching, facial or tongue swelling, which makes it difficult to breathe or swallow, while others may experience nausea and vomiting. These symptoms may begin within seconds, minutes or hours after exposure to the allergen. The best prevention method for anaphylaxis is avoidance of the specific allergen(s).

When a severe, life-threatening allergic reaction occurs, epinephrine should be administered immediately and patients and caregivers should seek immediate medical attention. Patients and caregivers should always carry and know how to use an epinephrine auto-injector to treat emergency allergic reactions. Without treatment, anaphylaxis can result in death within a matter of minutes.

#### **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, rare diseases, consumer healthcare, emerging markets and animal health. 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, 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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<sup>1</sup> Auvi-Q PI. Section 1. Indications and Use

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