# Sanofi Announces FDA Approval for Auvi-Q™, First Voice-guided Epinephrine Auto-injector for Patients with Life-threatening Allergies

*– Breakthrough device design talks patients and caregivers through the injection process –*

**Paris, France – August 13, 2012 –** Sanofi (EURONEXT: SAN and NYSE: SNY) announced today that the U.S. Food and Drug Administration (FDA) has approved Auvi-Q (epinephrine injection, USP) for the emergency treatment of life-threatening allergic reactions in people who are at risk for or have a history of anaphylaxis. Auvi-Q is the first-and-only compact epinephrine auto-injector with audio and visual cues that guide patients and caregivers step-by-step through the injection process.

Sanofi US licensed the North American commercialization rights to Auvi-Q from Intellijject, Inc., which has retained commercialization rights for the rest of the world.

*"As a company committed to patient-centered care, our focus is on creating innovative solutions that make a difference in the lives of people,"* said Anne Whitaker, President, North America Pharmaceuticals, Sanofi US. *"Auvi-Q delivers on this by offering a state-of-the-art epinephrine auto-injector device that addresses the needs of patients at risk for life-threatening allergic reactions and their caregivers."*

While recently updated guidelines emphasize the importance of the life-saving role of epinephrine, surveys showed 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 device during an emergency.

*"With this FDA approval, Auvi-Q will become the first-and-only epinephrine auto-injector that talks users through each step of the injection process,"* said Bryan Downey, Vice President, Auvi-Q, Sanofi US. *"We are confident that Auvi-Q will provide the up to six million Americans at risk for anaphylaxis and their caregivers an easy-to-use, compact option with unique features to help manage a life-threatening allergic reaction."*

Auvi-Q contains epinephrine, a well-established, first-line treatment for severe, life-threatening allergic reactions that may occur as a result of exposure to allergens including nuts, shellfish, dairy, eggs, insect bites, latex and medication, among other allergens.

*"The first step in preventing a severe allergic reaction is always avoidance of the specific allergen,"* said Dr. Vivian Hernandez-Trujillo, a pediatric allergist and national expert in anaphylaxis. *"However, in the event of a life-threatening allergic reaction, it's important to know how to respond quickly. Auvi-Q offers patients and caregivers guidance through the injection process."*

**About Auvi-Q™**
Auvi-Q (epinephrine injection, USP) is used to treat life-threatening allergic reactions (anaphylaxis) in people who are at risk for or have a history of these reactions. Auvi-Q is the size and shape of a credit card, the thickness of a cell phone and fits comfortably in a pocket or small purse.

During a life-threatening allergic reaction, Auvi-Q talks the user through each step of the injection process. If the patient or caregiver needs more time, it repeats the step-by-step directions. Alternatively, a patient or caregiver can move at their own pace by following the written instructions printed on the device.

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. In addition to being an auto-injector, Auvi-Q 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.

Eric and Evan Edwards, twin brothers who suffer from life-threatening allergies, and co-founders of Intellijject, 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.

**Important Safety Information**
Auvi-Q (epinephrine injection, USP) is for immediate self (or caregiver) administration and does not take the place of emergency medical care. Seek immediate medical treatment after use. Each Auvi-Q contains a single dose of epinephrine. **Auvi-Q should only be injected into your outer thigh**. DO NOT INJECT INTO BUTTOCK OR INTRAVENOUSLY. If you accidentally inject Auvi-Q into any other part of your body, seek immediate medical treatment. Epinephrine should be used with caution if you have heart disease or are taking certain medicines that can cause heart-related (cardiac) symptoms.

**If you take certain medicines, you may develop serious life-threatening side effects from epinephrine**. Be sure to tell your doctor all the medicines you take, especially medicines for asthma. Side effects may be increased in patients with certain medical conditions, or who take certain medicines. These include asthma, allergies, depression, thyroid disease, Parkinson's disease, diabetes, high blood pressure, and heart disease.

The most common side effects may include increase in heart rate, stronger or irregular heartbeat, sweating, nausea and vomiting, difficulty breathing, paleness, dizziness, weakness or shakiness, headache, apprehension, nervousness, or anxiety. These side effects go away quickly, especially if you rest.

Talk to your healthcare professional to see if Auvi-Q™ is right for you.

Please see www.Auvi-Q.com for full prescribing information, and to sign up for more information.

**Clinical Study Background**
A bioequivalence clinical study was conducted using Auvi-Q (epinephrine injection, USP) and EpiPen®. Both auto-injectors delivered 0.3mg of epinephrine. Injections with epinephrine using Auvi-Q were well tolerated and resulted in epinephrine plasma concentration levels that were found to be bioequivalent to EpiPen®.

**About Anaphylaxis**
Anaphylaxis (pronounced ana-fuh-lax-is) is a serious allergic reaction that happens quickly and may cause death. It can occur as a result of exposure to allergens including nuts, shellfish, dairy, eggs, insect bites, latex and medication, among other allergens. Food is the most commonly-identified anaphylaxis trigger and accounts for 30 percent of all anaphylaxis fatalities.

According to the 2010 American Academy of Allergy Asthma & Immunology Practice Parameters, up to six million Americans may be at risk for anaphylaxis, although the precise incidence of anaphylaxis is unknown and is likely underreported. Numerous studies indicate that the rate of anaphylaxis has increased in recent years, particularly among those under 20.

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 breath 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 of 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, 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 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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