Sanofi Canada Issues Voluntary Nationwide Recall of Allerject® Due to Potential Inaccurate Dosage Delivery

FOR IMMEDIATE RELEASE

Laval, Quebec – October 28th, 2015 - Sanofi-aventis Canada Inc. (Sanofi Canada**)** is recalling all Allerject® (epinephrine injection, USP). The voluntary recall involves all Allerject currently on the market and includes both the 0.15 mg/ 0.15 mL and 0.3 mg/0.3 mL strengths for hospitals, retailers and consumers. The products have been found to potentially have inaccurate dosage delivery.

If a patient who is experiencing a serious allergic reaction (i.e., anaphylaxis) did not receive the intended dose, there could be significant health consequences, including death because anaphylaxis is a potentially life-threatening condition.

As of October 26, 2015, Sanofi US and Canada have received 26 reports of suspected device malfunctions from an estimated 2,784,000 units distributed in North America.

Specifically, in Canada, 9 suspected device malfunctions were reported out of an estimated 492,000 units distributed. None of these device malfunction reports have been confirmed. In these reports, patients have described symptoms of the underlying hypersensitivity reaction. No fatal outcomes have been reported among these cases.

Allerject (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. All Allerject units are being recalled.

Sanofi Canada is proactively communicating with wholesalers, pharmacists, patients and caregivers, patient associations, and hospitals to inform them of this precautionary voluntary recall and how to proceed.

Sanofi Canada is actively working with suppliers of alternative epinephrine auto-injectors to have a full stock available in Canada as soon as possible.

Canadian customers are asked to immediately return the product to their local pharmacy to obtain an alternate epinephrine auto-injector. In the absence of availability of an alternate epinephrine auto-injector, patients are instructed to retain their Allerject device until an alternate auto-injector is available.

In light of the need to manage supply associated with this recall, we are asking customers and pharmacists to limit the replacement of Allerject to one unit or the appropriate number of units as instructed by your healthcare professional until full alternative stock is available.

If patients are unable to obtain supplies of alternative epinephrine auto-injectors, and in the event of a life-threatening allergic reaction (anaphylaxis), patients who do not have a replacement product should use their Allerject device, call 911 and immediately seek emergency medical services, in accordance with current product labelling.

Sanofi Canada is committed to patient safety and the quality of Allerject, and will continue to work closely with our partners and regulatory authorities to resolve this issue in a timely manner.

Any questions or concerns regarding this voluntary product recall, please contact the Allerject Call Center at 1-855-405-4321.

Any adverse events that may be related to the use of these products should be reported either to:

Sanofi Canada
Phone: 1-855-405-4321

Health Canada
Phone: 1-866-234-2345

MedEffect Canada website:
http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php

This recall is being conducted with the knowledge of Health Canada.

Important Safety Information
Indication

Allerject® is indicated for the emergency treatment of anaphylactic reactions in patients who are determined to be at increased risk for anaphylaxis, including individuals with a history of anaphylactic reactions.

Important Safety Information

Allerject is for immediate self (or caregiver) administration and does not take the place of emergency medical care. Seek immediate medical treatment after use. Each Allerject contains a single dose of epinephrine. **Allerject should only be injected into your outer thigh**. DO NOT INJECT INTO BUTTOCK OR INTRAVENOUSLY. If you accidentally inject Allerject 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 about 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.

You are encouraged to report negative side effects of prescription drugs.

In Canada, please call 1-866-234-2345 or visit http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php.

Please click here (Canada) for Full Prescribing Information.

About Sanofi – www.sanofi.ca
Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

Sanofi entities in Canada include Sanofi Canada (pharmaceuticals), Sanofi Pasteur (vaccines), Sanofi Consumer Health (cosmeceuticals, over-the-counter products and specialty care), Genzyme (rare diseases) and Merial (animal health). Together they employ close to 1,700 people. In 2014 Sanofi companies invested $130.5 million in R&D in Canada, creating jobs, business and opportunity throughout the country.

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