



For Canadian media only

## Sanofi to Return Allerject® (epinephrine injection, USP) Rights to kaléo

**Laval, Qc. - February 23, 2016** - Sanofi (EURONEXT : SAN and NYSE : SNY) announced today that the License and Development Agreement between Sanofi and kaléo, formerly Intelliject Inc., the developer of Auvi-Q® and Allerject® (epinephrine injection, USP) , will terminate later this year. At that time, all U.S. and Canadian rights will be returned to kaléo. Sanofi is in discussions with kaléo on these terms and for an orderly transition plan. kaléo will evaluate timing and options for bringing Allerject back to the Canadian market.

The decision to return rights for Allerject aligns with Sanofi's ongoing transformation to focus on critical therapeutic areas in its five global business units: Diabetes & Cardiovascular, General Medicines & Emerging Markets, Sanofi Genzyme, Sanofi Pasteur and Merial. Sanofi Canada will complete the nationwide voluntary recall process announced October 28, 2015. For more information on the voluntary recall, please visit [allerject.ca](http://allerject.ca).

### 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 Canada – [www.sanofi.ca](http://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 the Diabetes and Cardiovascular Diseases Business Unit, the General Medicines, Established Products and Consumer Healthcare Business Unit, Sanofi Pasteur (vaccines), Sanofi Genzyme (rare diseases, multiple sclerosis and oncology) 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.

## About Sanofi US

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 is the holding company of a consolidated group of subsidiaries and operates in the United States as Sanofi US. For more information on Sanofi US, please visit <http://www.sanofi.us> and <http://www.news.sanofi.us/social-media> 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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