



SANOFI

Press Release

Source: Sanofi (EURONEXT: SAN) (NYSE: SNY)

FDA Approves Sanofi's Admelog[®] (insulin lispro injection)

- * First FDA-approved follow-on mealtime insulin
- * Admelog (insulin lispro injection) 100 Units/mL will be available in U.S. in vial and SoloStar pen

Paris, France - December 11, 2017 – The U.S. Food and Drug Administration (FDA) has approved Sanofi's Admelog[®], the first follow-on insulin lispro to help people living with diabetes manage blood sugar levels at mealtime.

"Sanofi has a deep heritage and broad experience in providing treatments for people living with diabetes. Complementing our existing insulin portfolio, Admelog will offer a more affordable option for those who require control of their blood sugar levels at mealtime," said Stefan Oelrich, Executive Vice President and Head, Global Diabetes and Cardiovascular, Sanofi. "The approval of Admelog is an important milestone for Sanofi in our mission to serve patients living with chronic diseases such as diabetes."

Admelog is a rapid-acting insulin similar to Humalog[®], another insulin lispro 100 Units/mL, currently approved in the U.S. The Admelog clinical development program involved more than 1,000 adults living with type 1 or type 2 diabetes. Admelog will be available in both vials and the SoloStar pen, which is the most-used disposable insulin pen platform in the U.S.

Admelog was also granted marketing authorization as a biosimilar, under the proprietary name, Insulin lispro Sanofi[®], by the European Commission in July 2017.

What is Admelog (insulin lispro injection)?

Prescription Admelog is a fast-acting human insulin used to improve blood sugar control in adults with Type 2 diabetes and adults and children (3 years and older) with Type 1 diabetes.

About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.



With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

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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 regarding the marketing and other potential of the product, or regarding potential future revenues from the product. 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, unexpected regulatory actions or delays, or government regulation generally, that could affect the availability or commercial potential of the product, the absence of guarantee that the product will be commercially successful, the uncertainties inherent in research and development, including future clinical data and analysis of existing clinical data relating to the product, including post marketing, unexpected safety, quality or manufacturing issues, competition in general, risks associated with intellectual property and any related future litigation and the ultimate outcome of such litigation, and volatile economic conditions, as well as those risks 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, 2016. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.