Sanofi Receives CHMP Recommendation for Approval of Insulin Lispro Biosimilar

- Positive opinion based on a clinical development program involving over 1,000 people with type 1 or type 2 diabetes -

Paris, France – May 19, 2017 - Sanofi announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion for the marketing authorization of Insulin lispro Sanofi® (insulin lispro 100 Units/mL). CHMP recommended the use of Insulin lispro Sanofi® to treat adults and children who have diabetes and need insulin to keep their blood sugar level controlled, including those patients whose diabetes has just been diagnosed. This positive opinion is the company's first major regulatory milestone for a biosimilar diabetes treatment.

"*We welcome the CHMP positive opinion for Insulin lispro Sanofi® and look forward to the final decision of the European Commission (EC),*" said Jorge Insuasty MD, Senior Vice President, Global Head of Development, Sanofi. "*Our development of this investigational biosimilar product reflects Sanofi's expertise and long-term heritage in developing and manufacturing high-quality insulins for people with type 1 or type 2 diabetes and their physicians.*"

The recommendation is based on a clinical development program involving over 1,000 adults with type 1 or type 2 diabetes. This program comprised a pharmacokinetic / pharmacodynamic (PK/PD) Phase 1 study to evaluate the product's similarity in exposure and activity compared to insulin lispro 100 Units/mL as currently approved in the U.S. and EU[1], two multi-center Phase 3a clinical trials (SORELLA 1[2] and SORELLA 2) evaluating its safety and efficacy compared to insulin lispro 100 Units/mL as currently approved in the U.S. and EU in adults with type 1 or type 2 diabetes, and a safety study in insulin pumps in adults with type 1 diabetes.

"Insulin lispro is an important and widely-used treatment for people with diabetes who require rapid control of their blood sugar at mealtime," said Peter Guenter, Executive Vice President and General Manager, Diabetes & Cardiovascular, Sanofi. *"By broadening our portfolio of quality insulin options, we acknowledge our commitment to expand the affordability and sustainability of insulin treatments."*

The European Commission is expected to make a final decision on marketing authorization for Insulin lispro Sanofi® in the coming months.

About Insulin lispro Sanofi® (insulin lispro 100 Units/mL)

Insulin lispro Sanofi® is a biosimilar of insulin lispro, a rapid-acting insulin analog, produced using recombinant DNA technology and has the identical amino acid sequence as its reference product. It is currently not approved by any regulatory authority. It was submitted to the European Medicines Agency (EMA) in September 2016.

About Sanofi

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi is organized into five global business units: Diabetes and

Cardiovascular, General Medicines and Emerging Markets, Sanofi Genzyme, Sanofi Pasteur and Consumer Healthcare. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

References

1. Kapitza C et al, Similar pharmacokinetics and pharmacodynamics of rapid-acting insulin lispro products SAR342434 and US- and EU-approved Humalog in subjects with type 1 diabetes. Diabetes Obes Metab. 2017 May;19(5):622-627.
2. Garg SK et al, Abstract #863 presented at European Association for the Study of Diabetes (EASD) 52nd Annual Meeting, September 2016. Available via http://www.easdvirtualmeeting.org/resources/similar-glucose-control-post-prandial-glucose-excursions-and-safety-in-people-with-type-1-diabetes-mellitus-on-mdi-using-sar342434-or-insulin-lispro-and-insulin-glargine-u100-sorella-1-study [Accessed April 2017].

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 clinical development of and potential marketing approvals for the product. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans", "will be" 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 of the product, 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 the product as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of the product, the absence of guarantee that the product if approved will be commercially successful, risks associated with intellectual property, future litigation, the future approval and commercial success of therapeutic alternatives, 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.

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