

# Press Release

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

## EMA to review sotagliflozin as potential treatment for type 1 diabetes

**Paris – March 29, 2018** - The European Medicines Agency (EMA) has accepted for review Sanofi's regulatory submission for sotagliflozin. If approved, the oral treatment would be used as an addition to insulin therapy to improve blood sugar control in adults with type 1 diabetes mellitus. Developed in partnership with Lexicon Pharmaceuticals, Inc., sotagliflozin is an investigational dual inhibitor of SGLT-1 and SGLT-2, proteins that influence how the intestines and kidneys process blood sugar (glucose).

*“Despite recent advances, the challenges of type 1 diabetes management prevent many patients from reaching their treatment goals. There is a need for therapies to be used in addition to insulin to help people with type 1 diabetes better control their blood sugar. Sotagliflozin is the first SGLT-1/2 dual inhibitor to be accepted for regulatory review in Europe,”* says Jorge Insuasty, Senior-Vice President, Global Head of Development, Sanofi. *“We look forward to working with the EMA through the review process to bring this potential treatment to patients.”*

The Marketing Authorization Application submitted to EMA is based on data from the inTandem clinical trial program which consists of three Phase 3 clinical trials assessing the safety and efficacy of sotagliflozin in approximately 3,000 adults with inadequately controlled type 1 diabetes.<sup>1-3</sup> Its safety and efficacy have not been fully evaluated by any regulatory authority.

### References

1. Buse J et al, Presentation 69-OR at American Diabetes Association 77th Scientific Sessions (ADA 2017), San Diego, CA, U.S.
2. Danne T. Presentation 185-OR at European Association for the Study of Diabetes Annual Meeting (EASD 2017), Lisbon, Portugal.
3. Garg SK, et al. N Engl J Med 2017; 377:2337-2348, DOI: 10.1056/NEJMoa1708337.

### 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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[ir@sanofi.com](mailto:ir@sanofi.com)**Sanofi Forward-Looking Statements**

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