SANOFI

Press Release
UNITED STATES

Sanofi to conduct precautionary voluntary recall of Zantac OTC in U.S. and Canada

BRIDGEWATER, NJ – October 18, 2019 – As a precautionary measure, Sanofi will conduct a voluntary recall of Zantac OTC (over-the-counter) in the U.S. and Canada. This recall is being taken due to possible contamination with a nitrosamine impurity called N-nitrosodimethylamine (NDMA). The company is working with health authorities to determine the level and extent of the recall.

On September 13, 2019, the U.S Food and Drug Administration and Health Canada issued public statements alerting that some ranitidine medicines, including Zantac OTC, could contain NDMA at low levels and asked manufacturers to conduct testing.

Evaluations are ongoing on both drug substance (active ingredient) and finished drug product. Due to inconsistencies in preliminary test results of the active ingredient used in the U.S. and Canadian products, Sanofi has made the decision to conduct the voluntary recall in the U.S. and Canada as the investigation continues.

Active ingredients used in Sanofi's ranitidine products outside of the U.S. and Canada are sourced from different suppliers. Sanofi is committed to transparency and will continue to communicate results with health authorities from the ongoing testing, and work with them to make informed decisions based on available data and evidence.

Sanofi encourages anyone using Zantac OTC to speak with their health care providers or pharmacists if they have any additional questions.

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 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, 2018. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.