

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

LAVAL, QC, Oct. 18, 2019 /CNW Telbec/ - As a precautionary measure, Sanofi will conduct a voluntary recall of Zantac OTC (over-the-counter) in Canada and the U.S. This recall is being taken due to possible contamination with a nitrosamine impurity called N-nitrosodimethylamine (NDMA) and will be initiated, in Canada, at the pharmacy and retail store level.

On September 13, 2019, Health Canada and the U.S Food and Drug Administration 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 U.S. and Canadian products, Sanofi has made the decision to conduct the voluntary recall in Canada and the U.S. as the investigation continues.

Active ingredients used in Sanofi's ranitidine products outside Canada and the U.S. 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 pharmacist 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 entities in Canada employ more than 2,000 people. In 2018, we invested \$127.4 million in R&D in Canada, creating jobs, business and opportunity throughout the country.

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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 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, Sanofi's ability to benefit from external growth opportunities, to complete related transactions and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic conditions, the impact of cost containment initiatives 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, 2018. 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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