

Media Update



Paris, August 11, 2022.

In response to the recent highly speculative news flow regarding the U.S. Zantac litigation at a time when there have not been any material developments, Sanofi remains confident in its legal defenses and wishes to make the following statement, consistent with what has been disclosed previously:

On September 13, 2019, FDA issued a statement alerting the public that some ranitidine medicines, including over-the-counter Zantac, contained a nitrosamine impurity called N-nitrosodimethylamine (NDMA) at low levels. NDMA is a known environmental contaminant found in drinking water, soil, and common foods, including meats, dairy products, and vegetables. People are routinely exposed to small amounts of NDMA every day. FDA subsequently announced that its preliminary testing showed NDMA levels exceeded FDA's allowable limit in some of the samples it tested.

Upon receipt of this information, however, Sanofi quickly mobilized, ran additional confirmatory testing, and out of an abundance of caution issued a voluntary recall of all ranitidine Zantac OTC products in the U.S. and Canada.

Since 2019, the medical, scientific, and regulatory communities have extensively evaluated the safety of Zantac's active ingredient ranitidine, and the data shows there is no evidence of consumer harm from real-world use of Zantac. Over time, both [FDA](#) and the [European Medicines Agency](#) have evaluated the available data and found no evidence that ranitidine causes cancer.

Regardless of the scientific evidence, within days of FDA's 2019 announcement, purported class actions and personal injury lawsuits were filed in US courts, seeking economic damages or alleging that Zantac caused various cancers. However, given that Sanofi acted responsibly at all times and the lack of scientific support for plaintiffs' claims, Sanofi is fully confident in its defenses to the litigation. Sanofi stands by the safety of the medicine today.

Importantly, Sanofi acquired the OTC rights to Zantac less than three years before these lawsuits commenced, and after the medicine had been on the market for more than 35 years. In addition to Sanofi, three other companies that marketed Rx and/or branded OTC Zantac over time -- GSK, Pfizer, and Boehringer Ingelheim -- are also named as defendants in these actions. Other additionally named defendants have included dozens of generic manufacturers, retailers, and pharmaceutical distributors.

The first trial that may involve Sanofi as a defendant is currently scheduled for February 2023 as a part of the California state court proceedings. Sanofi is not a defendant in many of the other cases currently set for trial.

Sanofi's sales of Zantac account for only a very small percentage of the product's total sales over the 35+ years that Rx and OTC Zantac was available. Potential historical brand liability was not all passed to Sanofi upon its acquisition of Zantac. Sanofi acquired the marketing rights to Zantac from Boehringer Ingelheim in 2017. Boehringer Ingelheim continued to manufacture Zantac during the period Sanofi marketed the product.

As to the respective indemnification rights and obligations of Sanofi in the context of its acquisition of the product from Boehringer Ingelheim, those obligations are being disputed between the parties in the arbitration. The arbitration award is expected to be rendered around year-end 2022. Regardless of the arbitration outcome, the legal defenses in the US litigation are strong.

As of August 1, 2022, Sanofi was aware of approximately 2,850 personal injury plaintiffs across both state and federal jurisdictions with filed cases naming Sanofi in addition to other defendants. When factoring in additional Zantac cases that do not involve Sanofi, Sanofi is aware of approximately 3,450 total personal injury plaintiffs across all jurisdictions. There are other potential personal injury claimants who, in lieu of filing a court case, have instead joined a registry of "unfiled" claims established by the federal MDL court. The data on these potential cases remain preliminary and unverified and subject to change. It remains unknown how many unfiled claimants who have participated in the Registry may file suit, or whether any of those claimants will name Sanofi as a defendant in any such suits. Over time, the number of unfiled claims alleging either Rx and/or OTC use and implicating a variety of defendants in these actions has exceeded 150,000 – a significant number of these claims, however, do not implicate Sanofi.

The science does not support the plaintiffs' claims in this litigation. There is no reliable evidence that Zantac causes any of the alleged injuries under real-world conditions, and Sanofi remains fully confident in its defenses. Given the strength of our case and the uncertainty of future proceedings no contingencies have been established.

About Sanofi

We are an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people's lives. Our team, across some 100 countries, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible. We provide potentially life-changing treatment options and life-saving vaccine protection to millions of people globally, while putting sustainability and social responsibility at the center of our ambitions.

Sanofi is listed on Euronext: SAN and NASDAQ: SNY

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Sanofi Forward-Looking Statements

This media statement 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, risks associated with pending or future litigation and the ultimate outcome of such litigation, the uncertainties

inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or EMA, volatile economic and market conditions. The risks and uncertainties also include the uncertainties 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, 2021. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.