Press Release

Sanofi prevails in Zantac arbitration initiated by Boehringer Ingelheim

- Arbitral tribunal dismisses claim brought by Boehringer Ingelheim ("BI") against Sanofi for indemnification of potential liabilities related to the ongoing Zantac litigation in the U.S. ; decision is final and cannot be appealed
- Key U.S. federal court ruling in December 2022 found no reliable evidence that Zantac causes the alleged injuries, bolstered similar findings by FDA and EMA; tens of thousands of claimants have abandoned their claims
- Sanofi remains highly confident in defense of underlying U.S. Zantac litigation as confirmed by developments over the last 6 months

Paris, June 20, 2023. Sanofi announces that in an International Chamber of Commerce dispute, the tribunal dismissed BI's indemnification claim against Sanofi and confirmed that Sanofi shall not be liable to indemnify BI for any potential losses in relation to the ongoing Zantac litigation in the U.S. This decision is final and non-appealable.

Importantly, Sanofi remains confident that the defense of the underlying U.S. Zantac litigation is very strong. There is no reliable scientific evidence that Zantac causes the alleged injuries in the cases brought against GSK, Pfizer, BI, Sanofi, and others in the U.S. litigation. The FDA and the European Medicines Agency have both evaluated the available data and found no evidence that ranitidine, the active ingredient contained in Zantac, causes cancer.

This was notably confirmed in December 2022, when a U.S. federal court assigned to oversee all federal cases in the United States ("MDL") ruled that plaintiffs had no reliable scientific evidence that ranitidine can cause any of the plaintiffs' alleged injuries. The thorough ruling substantiated Sanofi's scientific defenses demonstrating that there is no reliable evidence of causation for even those cancer types that plaintiffs claimed had the strongest evidence. Sanofi believes that any appeal by plaintiffs of the MDL ruling has a low probability of success. Tens of thousands of claimants who were once a part of this MDL litigation chose to abandon their claims or else withdrew early from the MDL, either filing in state court or not re-filing at all. These recent events have significantly decreased the potential scope of the litigation.

Background

Zantac was launched in the United States as a prescription medication by GSK in 1983 (GSK continued to market the Rx version until 2017). In 1995, GSK launched an OTC version of its Zantac 75mg formula. In 1997, generic ranitidine entered the market. In 1998, Pfizer acquired the OTC rights and in 2004 it launched a 150mg version of the product as well. In 2006, BI acquired the U.S. OTC rights for Zantac and in January 2017 Sanofi acquired those OTC rights.

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.
In October 2019, out of an abundance of caution Sanofi issued a voluntary recall of all ranitidine Zantac OTC products in the U.S. and Canada.

Since that time, the medical, scientific, and regulatory communities have extensively evaluated the safety of Zantac's active ingredient ranitidine, and the data show 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 have also found no evidence that ranitidine causes cancer.

Regardless of the scientific evidence, within days of FDA's September 2019 announcement, purported class actions and personal injury lawsuits were filed in U.S. courts, alleging that Zantac caused various cancers. In addition to Sanofi, these lawsuits named GSK, Pfizer, BI, dozens of generic manufacturers, retailers and pharmaceutical distributors.

The arbitration dispute arose from contractual indemnification obligations agreed between Sanofi and BI as part of the January 2017 swap of Sanofi's Animal Health business for BI's Consumer Health Care business.

There is no evidence of consumer harm from real-world use of Zantac as a result of any NDMA contamination.

Sanofi stands by the safety of Zantac. Given the lack of scientific support for plaintiffs' claims, Sanofi remains fully confident in its defenses to the litigation. Sanofi acted responsibly at all times.

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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