



Paris, June 16, 2023.

The health of all those treated and impacted by our medicines is our priority.

A post-authorisation safety study (PASS) has recently assessed the potential risk of neurodevelopmental disorders in children whose fathers were treated with valproate monotherapy in the three months before conception, compared with the risk in children whose fathers were treated with two other epilepsy monotherapy treatments, lamotrigine or levetiracetam, in the three months before conception.

This PASS is a retrospective observational study based on electronic medical records from three Nordic countries, which was requested by the EMA (European Medicines Agency) and designed together with the pharmaceutical companies marketing valproate-containing products.

Initial results have been shared with the EMA for their evaluation, and the health authorities in all countries where we have a marketing authorization.

Sanofi considers that the study has limitations. A thorough data review process has shown that new analyses need to be performed before final conclusions can be drawn from the study. We have informed health authorities of this situation and are working diligently with them.

If patients have any concerns, they should discuss them with their treating physician. Discontinuing treatment carries the risk of recurrent seizures or may worsen the symptoms of bipolar disorder.

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#### *About Depakine*

Depakine (sodium valproate) is a broad-spectrum anti-epileptic that has been prescribed for more than 50 years and remains a reference treatment for epilepsy worldwide. Depakine is also a mood stabilizer, registered in the treatment of manic episodes associated with bipolar disorder. Sanofi holds no rights to Depakine in the U.S., and sodium valproate generics are available in most markets.

#### *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.

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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 EMA, and volatile 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.