Information on Post Authorization Safety Study regarding potential risk of neurodevelopmental disorders in children whose fathers were treated with valproate.

Paris, April 15, 2024

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

A post-authorization safety study (PASS) has 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 Pharmacovigilance Risk Assessment Committee (PRAC) of the EMA (European Medicines Agency) and designed together with the pharmaceutical companies marketing valproate-containing products.

Following the assessment of the final results and study conclusions, the Consortium of MAHs' submitted a proposal to revise the product information and to implement additional risk minimization measures for males, on a precautionary basis.

The PRAC's assessment of the study results and proposed precautionary measures for male patients using valproate containing medicines is now finalized and reflects most of the measures proposed in this submission.

The study protocol and study results are available on the HMA-EMA Catalogues of real-world data.

The PRAC's conclusions are available on the EMA website.

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.

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.

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 fact that product may not 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 future litigation and the ultimate outcome of such litigation, and volatile economic and market conditions, and the impact that pandemics or other global crises may have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. 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, 2023. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.