



Paris, June 16, 2023.

La santé de toutes les personnes traitées par nos médicaments est notre priorité.

Une étude de sécurité post-autorisation (PASS) a récemment évalué le risque potentiel de troubles neurodéveloppementaux chez les enfants dont les pères ont été traités par valproate en monothérapie dans les trois mois précédant la conception, par rapport au risque chez les enfants dont les pères ont été traités par deux autres traitements de l'épilepsie en monothérapie, la lamotrigine ou le levetiracetam, dans les trois mois précédant la conception.

Cette étude PASS est une étude observationnelle rétrospective basée sur les dossiers médicaux électroniques de trois pays nordiques. Elle a été demandée par l'Agence Européenne des Médicaments (EMA) et conçue en collaboration avec les sociétés pharmaceutiques qui commercialisent des produits contenant du valproate.

Les premiers résultats ont été communiqués à l'EMA pour évaluation, ainsi qu'aux autorités de santé de tous les pays où nous disposons d'une autorisation de mise sur le marché.

Sanofi considère que cette étude présente des limites. Un processus d'examen approfondi des données a montré que de nouvelles analyses doivent être effectuées avant de pouvoir tirer des conclusions définitives de l'étude. Nous avons informé les autorités de santé de cette situation et travaillons avec diligence avec elles.

Si les patients ont des questions, ils doivent en discuter avec leur médecin traitant. L'arrêt du traitement expose les patients à la réapparition des crises convulsives ou peut aggraver les symptômes du trouble bipolaire.

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 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.