Paris, August 30, 2022.
Regarding the ongoing Depakine® (sodium valproate) product litigation in France, Sanofi is issuing the following statement, consistent with what has been disclosed previously:

Depakine® is a medicine that has significantly improved the treatment of epilepsy around the world since its first introduction on the market in 1967 in France. It is still considered as one of the most effective medicines to treat many forms of epilepsy, including the most severe. For some epileptic patients, it remains the only effective treatment compared to other therapeutic alternatives available on the market. Notably, Depakine® is listed as an essential medicine by the WHO due to its "important role in the management of epilepsy and bipolar disorder".

Sanofi has been proactive and transparent with regards to Depakine® and requested the update of medical information for physicians and patients to Health Authorities. Pharmaceutical companies must first obtain approval from the local Health Authorities in order to change information documents pertaining to the drugs they commercialize and cannot act unilaterally.

In the 1980s, Sanofi provided information about the risk of malformation of the fetus and asked Health Authorities to modify the Depakine® information documents accordingly. Since then, information on risks of congenital malformations has been included in the information documents for healthcare professionals.

In the early 2000s, based on new scientific data concerning the occurrence of neurodevelopmental delay (NDD) in children exposed to Depakine® during pregnancy, Sanofi informed Health Authorities and requested, first in 2003, that the product information be modified to contain specifications on these emerging issues. After an initial refusal by the French Health Authority, another request was submitted in 2004 and the information documents for healthcare professionals were modified in January 2006 regarding this risk. In the patient product information, it was mentioned that prescription of sodium valproate for pregnant women was not recommended.

Importantly, in France, the local Health Agency did not agree to the update of the patient product information to include the risks of congenital malformations and NDD until 2010. Instead patients were asked to consult their physician in case of pregnancy or of a planned pregnancy. Starting 2006, the patient product information mentioned that Depakine was not recommended during pregnancy.

The description of the risks was included in the Summary of Product Characteristics (SmPC) earlier than in the Patient Leaflet (PIL), as per the Health Authority's decisions, considering that patients should not stop their treatment without medical supervision due to the risks it triggered (an abrupt interruption of an antiepileptic treatment during pregnancy could lead to the resurgence of epileptic seizures, likely to threaten the patient's life and endanger fetal development).

As part of its pharmacovigilance obligations and as scientific knowledge evolves, Sanofi continues to update the product information for healthcare professionals and patients under the oversight of Health Authorities.

As of December 31, 2021, 75 families brought a civil claim involving 127 people exposed in utero to sodium valproate against Sanofi seeking indemnification under French law for personal injuries allegedly suffered by children in connection with the use of sodium valproate by their mothers during pregnancy to treat their epilepsy. A criminal investigation is also ongoing for more than 5 years in which both Sanofi and the French Health Agency (ANSM) have been indicted. The civil proceedings involve several parties, not only Sanofi but also the French Health Agency, and in some cases the prescribing physicians.

A class action – the first of its kind in France in the health sector - was initiated in 2017 by a patient association called "APESAC" (Association d'Aide aux Parents d'Enfants souffrant du Syndrôme de l'Anti-Convulsivant).

A few other proceedings are on-going in other European countries (Spain, Switzerland, Belgium, Germany). To date, no definitive court rulings retaining Sanofi's liability has been issued.

The actions brought against Sanofi before the civil courts also involve Sanofi's insurers, which have not challenged their coverage.

Those legal proceedings are lengthy and there is no option available in the French legal regime for a full and final settlement. Sanofi, alongside its insurers, has no other option than continuing to defend the interests of the company before the respective courts.

Source:
WHO Model List of Essential Medicines 2021: https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2021.01

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.