Press Release

Xenpozyme® (olipudase alfa) approved in Japan, first and only approved therapy indicated to treat acid sphingomyelinase deficiency

- Xenpozyme represents first Sanofi therapy to be approved under the SAKIGAKE 'fast-track' designation
- Approval based on positive results from two separate clinical trials in children and adults demonstrating improvement in lung function (as measured by DLco) and reduction of spleen and liver volumes

Paris, March 28, 2022. The Japanese Ministry of Health, Labor, and Welfare (MHLW) has granted marketing authorization for Xenpozyme® (olipudase alfa) for the treatment of adult and pediatric patients with non-central nervous system (non-CNS) manifestations of acid sphingomyelinase deficiency (ASMD), a rare, progressive, and potentially life-threatening genetic disease. Xenpozyme is currently the only approved treatment for ASMD and represents Sanofi's first therapy to be approved under the SAKIGAKE (or "pioneer") designation, which is the Japanese government's regulatory fast-track pathway to promote research and development of innovative new medical products addressing urgent unmet medical needs.

> ***John Reed, M.D., Ph.D***
> Executive Vice President, Global Head of Research and Development, Sanofi
> *"Today's approval of Xenpozyme is a watershed moment for ASMD patients and their families, representing 20 years of research and the shared efforts of advocacy partners, clinicians, and patients. As the world's first medicine approved for ASMD, Xenpozyme offers a potentially transformative option for this historically neglected community. We are proud of this achievement and grateful that Japan's PDMA has recognized the significance of the unmet need that Xenpozyme addresses with the Sakigake designation. At Sanofi, we are working with health authorities globally, including the EU where olipudase alfa has PRIME designation and in the USA where this enzyme replacement therapy has Breakthrough designation, to rush this important medicine to ASMD patients around the world."*

Xenpozyme is a recombinant human acid sphingomyelinase enzyme developed to replace deficient or defective acid sphingomyelinase (ASM), an enzyme that allows for the breakdown of the lipid sphingomyelin. Accumulation of sphingomyelin in cells can cause harm to the lungs, spleen, and liver, as well as other organs, potentially leading to early death.

The approval of Xenpozyme in Japan is based on positive results from the ASCEND and ASCEND-Peds clinical trials, showing that Xenpozyme provided improvement in lung function (as measured by diffusing capacity of the lung for carbon monoxide, or DLco) and reduction of spleen and liver volumes, with a well-tolerated safety profile in adults and children with ASMD. These data were presented at the American Society of Human Genetics (ASHG) 2020 Virtual Meeting.

Xenpozyme has been evaluated in children and adults to treat non-CNS manifestations of ASMD type A/B and ASMD type B. Xenpozyme has not been studied in patients with ASMD type A.

Historically known as Niemann-Pick disease types A, A/B, and B, ASMD is a genetically-based, progressive, and potentially life-threatening disease. ASMD represents a spectrum of disease, with two types that may represent opposite ends of a continuum referred to as ASMD type A and ASMD type B. ASMD type A/B is an intermediate form that includes varying degrees of CNS involvement. Until now, no approved therapies for ASMD have been available anywhere in the world.

Outside of Japan, olipudase alfa is being evaluated by regulatory authorities around the world. A Biologics License Application (BLA) for olipudase alfa was accepted for Priority Review by the U.S. Food and Drug Administration (FDA), with a decision expected early Q3 2022. The European Medicines Agency (EMA) has awarded olipudase alfa the PRIority MEdicines (PRIME) designation, and a decision is anticipated in the second half of 2022.

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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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 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, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the fact that product candidates if approved may not be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi's ability to benefit from external growth opportunities, to complete related transactions and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic and market conditions, cost containment initiatives and subsequent changes thereto, and the impact that COVID-19 will 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. Any material effect of COVID-19 on any of the foregoing could also adversely impact us. This situation is changing rapidly and additional impacts may arise of which we are not currently aware and may exacerbate other previously identified risks. 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.