

New data at WMS 2023 reaffirm long-term efficacy of Nexviazyme® (avalglucosidase alfa) for the treatment of Pompe disease

- Findings include long-term data of up to nearly three years, as well as real-world evidence, across a wide range of patients and clinical circumstances
- Data add to the totality of evidence demonstrating Nexviazyme's value to the Pompe community

Paris, October 6, 2023. New data being shared this week by Sanofi at the 28th Annual Congress of the World Muscle Society (WMS) in Charleston, South Carolina, U.S., build upon the considerable body of evidence supporting the use of Nexviazyme® (avalglucosidase alfa) to treat a wide range of patients living with Pompe disease across various clinical circumstances. Nexviazyme is a monotherapy approved in the United States and other markets for the treatment of late-onset Pompe disease and is approved for infantile-onset Pompe disease in Europe and other countries. In the U.S., Nexviazyme is currently being evaluated in Phase 3 clinical trials for infantile-onset Pompe disease.

Data include research across people living with late-onset or infantile-onset Pompe disease, people who are treatment naïve (never before treated) or have switched from previous treatment with the long-time standard of care, alglucosidase alfa, which is marketed under the brand name Myozyme® or in the U.S. as Lumizyme®, and patients with varying baseline characteristics.

Of note, key data being shared at WMS stem from the Phase 3 COMET trial evaluating the long-term efficacy, safety and durability of Nexviazyme in those living with late-onset Pompe. The nearly three-year data demonstrate that patients who started treatment with Nexviazyme, whether treatment naïve or previously treated, had improvement or stabilization of respiratory function and mobility. Data also indicate that Nexviazyme was well tolerated by patients who switched from alglucosidase alfa.

Alaa Hamed, MD, MPH, MBA

Global Head of Medical Affairs, Rare Diseases

"Our findings being shared at WMS build upon existing evidence that supports the value of Nexviazyme in treating Pompe disease. With efficacy and safety demonstrated across a variety of patient cohorts, we remain confident in Nexviazyme as a compelling treatment option."

As part of a long-standing commitment to helping improve the lives of those living with rare diseases, Sanofi has been focused on providing treatments for people living with Pompe disease for more than 20 years, beginning with the development of the first approved treatment for this condition, Myozyme in 2006. Since then, Sanofi has continued to work closely with the Pompe community to help address unmet patient needs which resulted in the development of Nexviazyme.

People living with Pompe disease have low levels of the enzyme acid alpha-glucosidase (GAA), which results in build-up of glycogen in muscle cells throughout the body, which can lead to irreversible damage to skeletal and cardiac muscles.

Pompe disease can present as infantile-onset Pompe disease (IOPD), the most severe form of the disease with rapid onset in infancy, or late-onset Pompe disease (LOPD), which progressively damages muscles over time. If left untreated, IOPD can lead to heart failure and death within the first year of life, while people living with LOPD may require mechanical ventilation to help with breathing or a wheelchair to assist with mobility as the disease progresses.

About Nexviazyme (avalglucosidase alfa)

Nexviazyme (avalglucosidase alfa and avalglucosidase alfa-ngpt, in the U.S.) is an enzyme replacement therapy (ERT) designed to target the mannose-6-phosphate (M6P) receptor, the key pathway for uptake and transport of ERT. Nexviazyme aims to help improve uptake and enhance glycogen clearance in target tissues with an average 15-fold higher level of M6P moieties as compared to alglucosidase alfa, the comparator therapy in the pivotal study. Nexviazyme is approved in multiple markets around the world for the treatment of people living with Pompe disease, with specific indications varying by country. In the U.S., Nexviazyme is indicated for the treatment of late-onset Pompe Disease in patients 1 year of age and older. In Europe, the medicine is marketed under the brand name Nexviadyme and is indicated for the treatment of both late-onset and infantile-onset Pompe disease.

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

Media Relations

Sandrine Guendoul | + 33 6 25 09 14 25 | sandrine.quendoul@sanofi.com

Sally Bain | + 1 617 834 6026 | sally.bain@sanofi.com

Investor Relations

Eva Schaefer-Jansen | + 33 7 86 80 56 39 | eva.schaefer-jansen@sanofi.com

Arnaud Delépine | + 33 6 73 69 36 93 | arnaud.delepine@sanofi.com

Corentine Driancourt | + 33 6 40 56 92 21 | corentine.driancourt@sanofi.com

Felix Lauscher | + 1 908 612 7239 | felix.lauscher@sanofi.com

Tarik Elgoutni | + 1 617 710 3587 | tarik.elgoutni@sanofi.com

Nathalie Pham | + 33 7 85 93 30 17 | nathalie.pham@sanofi.com

Sanofi Forward-Looking Statements

This media update 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, 2022. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.