Press Release

Nexviadyme® (avalglucosidase alfa) approved by European Commission as a potential new standard of care for the treatment of Pompe Disease

- Approved for the treatment of the full spectrum of both late-onset Pompe disease and infantile-onset Pompe disease
- First new treatment option approved for the Pompe community in Europe in more than 15 years

Paris, June 28, 2022 – The European Commission has granted marketing authorization for Nexviadyme® (avalglucosidase alfa), an enzyme replacement therapy (ERT) for the long-term treatment of both late-onset and infantile-onset Pompe disease, a rare, progressive and debilitating muscle disorder. Nexviadyme is the first and only newly approved medicine for Pompe disease in Europe since 2006, when the European Commission authorized the marketing of alglucosidase alfa, branded Myozyme®.

> ***Benedikt Schoser, MD.***
> Senior Consultant and Professor, Friedrich-Baur-Institute, Department of Neurology, Ludwig-Maximilians-University Munich
> *"The approval of Nexviadyme in Europe to treat Pompe disease is backed by a robust body of evidence showing clinically meaningful improvements that can impact quality of life. The totality and rigor of the data is particularly noteworthy given the complexities of research and development for such a rare and progressive condition. Nexviadyme's demonstrated clinical benefit and molecular innovation bring a new treatment option to people living with Pompe disease who continue to face unmet needs."*

Addressing an unmet need for people living with Pompe disease

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 with LOPD may require mechanical ventilation to help with breathing or a wheelchair to assist with mobility as the disease progresses.

Nexviadyme now approved in many countries around the world

Nexviadyme is approved in multiple markets around the world for the treatment of certain people living with Pompe disease, including the European Union, the United States, Japan, Canada, Switzerland, Australia, Brazil, Taiwan and the United Arab Emirates. Outside of Europe, the treatment is marketed under the brand name Nexviazyme. In the U.S. and Japan, the majority of the Myozyme (alglucosidase alfa)-treated population has started, or is in the process of starting, treatment with Nexviazyme (avalglucosidase alfa).

In November 2021, Sanofi announced that as part of the European Medicines Agency's (EMA) review of Nexviadyme, the Committee for Medicinal Products for Human Use (CHMP) issued an opinion that the therapy does not qualify as a New Active Substance (NAS). In April 2022, the Committee for Orphan Medicinal Product (COMP) also recommended Nexviadyme be removed from the Community Register of Orphan Medicinal Products (OMP).

Sanofi strongly disagrees with both opinions and believes these conclusions were the result of an erroneous and very narrow interpretation of the NAS and OMP principles that demonstrate molecular innovation and clinical benefit. Sanofi stands by the totality of data in support of

Nexviadyme as a potential new standard of care and is concerned that such narrow interpretation will undermine rare disease incentive mechanisms in Europe. We believe withholding these distinct designations could negatively impact patient health in Europe by restricting access to innovative advancements in care.

Bill Sibold
Executive Vice President, Specialty Care, Sanofi
"For more than two decades, we've been working with the community and leveraging our scientific expertise to improve care for people living with Pompe disease. We strongly believe in the meaningful clinical benefits of this medicine as a new standard of care and will work hard to ensure the broadest possible access in Europe despite the European Commission's failure to recognize Nexviadyme's NAS and OMP designations. We call on patient advocacy groups, policymakers, clinicians and patients to join us in our efforts to ensure innovative treatments are appropriately recognized and made available to patients in Europe and beyond."

Nexviadyme, a new ERT for late-onset Pompe disease and infantile-onset Pompe Disease

Positive outcomes in key disease burden measures

In a robust clinical development program, Nexviadyme demonstrated clinically meaningful differences in key areas of disease burden for people living with late-onset Pompe disease and infantile-onset Pompe disease.

Results from the COMET study comparing Nexviadyme to alglucosidase alfa in LOPD at 49 weeks included:

- Patients treated with Nexviadyme showed a 2.9% improvement from baseline (SE=0.9) in forced vital capacity (FVC) percent-predicted, a key measure of respiratory function and the study's primary endpoint, which was 2.4% points greater as compared to the change with alglucosidase alfa. This difference exceeded the non-inferiority margin (p=0.0074; 95% CI, -0.13, 4.99). Statistical superiority was narrowly missed (p=0.06).
- Patients treated with Nexviadyme walked 32.2 meters farther (SE=9.9) compared to baseline in the 6-minute walk test (6MWT), a key secondary endpoint, which was 30 meters farther (p=0.040; 95% CI, 1.33, 58.69) than the change with alglucosidase alfa. Formal statistical testing for all secondary endpoints was not conducted.

Results from the Mini-COMET study evaluating Nexviadyme in IOPD patients showed improvement or stabilization at six months in efficacy outcomes, the trial's secondary objective, of gross motor function measure (GMFM-88), quick motor function test (QMFT), pediatric evaluation of disability index (Pompe-PEDI), left ventricular mass z-score (LVMZ), and eyelid position measurements in patients previously declining or insufficiently controlled with alglucosidase alfa.

A pooled safety analysis from four clinical studies found *serious* adverse reactions reported in patients treated with Nexviadyme included chills (1.4%), headache, dyspnoea, respiratory distress, nausea, skin discoloration, chest discomfort, pyrexia, blood pressure increased, body temperature increased, heart rate increased, and oxygen saturation decreased (0.7% each). Additionally, hypersensitivity reactions (43.5%), anaphylaxis (1.4%) and infusion-associated reactions (26.1%) were reported. The most *frequently* reported adverse drug reactions (ADRs) (>5%) were pruritus (9.4%), rash (8%), headache (7.2%), urticaria (6.5%), fatigue (6.5%), nausea (5.8%), and chills (5.1%).

Mechanism of action designed for increased uptake

People living with Pompe disease have low levels of the enzyme acid alpha-glucosidase (GAA), which results in build-up of glycogen, leading to irreversible damage to skeletal and cardiac muscles. Nexviadyme is specifically designed to target the mannose-6-phosphate (M6P) receptor, the key pathway for cellular uptake of ERT and transport to the lysosome, and has an

average 15-fold higher level of M6P moieties as compared to alglucosidase alfa. Nexviadyme aims to help improve uptake and enhance glycogen clearance in target tissues as compared to alglucosidase alfa, which was used as the comparator arm in the pivotal Phase 3 COMET study.

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 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 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.