Press Release

Sanofi's Nexviazyme met all primary and secondary endpoints in infantile-onset Pompe disease phase 3 study

- Nexviazyme met its primary endpoint, participants alive and free of invasive ventilation, in treatment-naïve infants zero to six months of age in the Baby-COMET phase 3 study
- Sanofi intends to submit the data to support a regulatory application in the US for the treatment of infantile-onset Pompe disease

Paris, June 30, 2026. Positive results from the Baby-COMET phase 3, single-arm, open-label study (clinical study identifier: NCT04910776), demonstrated that Nexviazyme (avalglucosidase alfa) met its primary endpoint: proportion of treatment-naïve pediatric participants six months of age and younger with infantile-onset Pompe disease (IOPD) alive and free of invasive ventilation at 52 weeks of treatment. In addition, the study met all secondary endpoints, including proportion of participants alive and free of invasive ventilation at 12 and 18 months of age, and numerical improvements in other metrics of disease progression at 52 weeks.

The results will be shared on July 8, 2026, at the 19th International Congress on Neuromuscular Diseases in Florence, Italy. In addition, the data will support a regulatory submission for a label extension in the US, anticipated in the second half of 2026.

Pompe disease is a rare, inherited/genetic, progressive neuromuscular disease caused by a deficiency of the acid alpha-glucosidase (GAA) enzyme that affects muscle function throughout the body. IOPD constitutes the most aggressive variant of this disease, manifesting with swift symptom progression during the first months of life. Without therapeutic intervention, IOPD results in severe and potentially fatal complications affecting the heart, breathing, and movement.

Nexviazyme is being evaluated as a potential treatment option for IOPD, designed to help enter cells and improve uptake of the essential GAA enzyme. This approach may help clear away excess glycogen, which builds up in muscle cells and can cause damage to skeletal and cardiac muscles.

In the Baby-COMET study, Nexviazyme was well tolerated and safety was consistent with the established profile of avalglucosidase alfa, with no serious treatment-related treatment-emergent adverse events, deaths, or discontinuations, and manageable infusion-associated reactions in 29.4% of participants.

> *"Infantile-onset Pompe disease is a devastating, rapidly progressive condition that presents within the first days or weeks of life, making early intervention critical to help improve invasive ventilator-free survival beyond one year,"* said **Priya S. Kishnani**, MD, C.L. and Su Chen Professor of Pediatrics; Medical Director, YT and Alice Chen Pediatrics Genetics and Genomics Center; and Division Chief, Medical Genetics, Duke University Medical Center, NC, US. *"The Baby-COMET study shows the potential of avalglucosidase alfa to support*

ventilator-free survival in infants, alongside encouraging cardiac and motor outcomes, offering important insights that may help advance the treatment landscape for these patients."

"These positive results offer the potential to expand access of Nexviazyme to more patients and families facing a condition with limited treatment options in the earliest months of life," said **Christopher Corsico**, Global Head of Development at Sanofi. *"The Baby-COMET findings are consistent with previous studies and reflect years of our scientific research aimed at translating deep biological understanding into clinical advances for the Pompe community."*

Nexviazyme is approved in multiple countries for the treatment of people living with Pompe disease, with specific indications varying by country. In the US, Nexviazyme was approved in 2021 for the treatment of late-onset Pompe disease (LOPD) in patients one year of age and older. In Europe, where the medicine is available under the name Nexviadyme, it received approval for the long-term enzyme replacement therapy of patients with Pompe disease (LOPD and IOPD) in 2022.

Nexviazyme in IOPD is currently under clinical investigation in the US, and its safety and efficacy in this indication have not been evaluated by the FDA.

About Pompe disease
People living with Pompe disease have low levels of the GAA enzyme, which results in build-up of glycogen in muscle cells throughout the body, leading to potentially irreversible damage to skeletal and cardiac muscles.

Pompe disease can present as either IOPD, the most severe form of the disease with early onset of symptoms in infancy that progress rapidly, or LOPD, which progressively damages muscles over time. 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
Nexviazyme (avalglucosidase alfa) is an ERT designed with high-binding affinity 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 approximately 15-fold higher level of M6P moieties compared with Myozyme/Lumizyme (alglucosidase alfa).

About the Baby-COMET study
The Baby-COMET phase 3 study is a single-arm, open-label, international, multicenter study evaluating Nexviazyme in treatment-naïve pediatric participants with IOPD 12 months of age and younger. Seventeen participants received intravenous Nexviazyme 40 mg/kg every other week. After a four-week screening period, participants received treatment for 52 weeks, followed by continued treatment for an additional 52 weeks and up to 104 additional weeks, with a four-week follow-up. The primary endpoint is the proportion of participants who are alive and free of invasive ventilation at week 52 of treatment. Key secondary endpoints included proportion of participants alive and free of invasive ventilation at 12 and 18 months of age, as well as change from baseline to week 52 in left ventricular mass Z-score, Alberta Infant Motor Scale score and urinary glucose tetrasaccharide.

About Sanofi

Sanofi is an R&D driven, AI-powered biopharma company committed to improving people's lives and delivering compelling growth. We apply our deep understanding of the immune system to invent medicines and vaccines that treat and protect millions of people around the world, with an innovative pipeline that could benefit millions more. Our team is guided by one purpose: we chase the miracles of science to improve people's lives; this inspires us to drive progress and deliver positive impact for our people and the communities we serve, by addressing the most urgent healthcare, environmental, and societal challenges of our time. Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

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Sanofi forward looking statement

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