Press Release

Sanofi's Infilbray approved in the US as the first medicine to treat neurological manifestations of Type 3 Gaucher disease

- Infilbray is a once-daily oral medicine that acts across the blood-brain barrier, targeting devastating neurological manifestations associated with GD3
- GD3 is a chronic neuronopathic form of the disease, characterized by CNS involvement, with patients worldwide

Paris, November 18, 2026. The US Food and Drug Administration has approved Infilbray (venglustat), a novel, oral glucosylceramide synthase inhibitor (GCSi) that acts across the blood-brain barrier, for the treatment of neurological manifestations of Type 3 Gaucher disease (GD3) in adults and pediatric patients weighing at least 15 kg. GD3 is a rare lysosomal storage disorder that causes progressive systemic and neurologic decline, with central nervous system (CNS) manifestations.

The approval is based on positive data from the LEAP2MONO phase 3 study (clinical study identifier: NCT05222906), in which Infilbray demonstrated improvements in neurological manifestations over the enzyme replacement therapy (ERT) imiglucerase, with a global test of multiple neurological endpoints showing statistically significant superiority (p=0.0137).

> *"Patients living with Type 3 Gaucher disease face a long and difficult road to accurate diagnosis, often going years without answers while neurological manifestations progress,"* said **Aviva Rosenberg**, JD, CEO and Co-Founder of the Gaucher Community Alliance. *"Today's Infilbray approval marks a long-awaited advancement for those experiencing devastating neurological symptoms of Type 3 Gaucher disease."*

The LEAP2MONO phase 3 study evaluated the efficacy and safety of Infilbray in adults and pediatric patients aged 12 years and older with neurological manifestations of GD3 who previously achieved stabilization of their systemic manifestations with ERT. The results demonstrated that patients receiving Infilbray achieved statistically significant improvements in certain neurological manifestations causing cognitive deficits and difficulty with coordination and balance, evaluated using multiple endpoints composed of the change from baseline to Week 52 in the modified Scale for the Assessment and Rating of Ataxia (SARA) (4-item SARA score) and the change from baseline to Week 52 in the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) total scale index score.

> *"Sanofi has brought novel medicines to people living with rare diseases for decades, and today's US approval of Infilbray for Type 3 Gaucher disease patients is an important addition to our broad portfolio,"* said **Manuela Buxo**, Executive Vice President, Global Head of Specialty Care at Sanofi. *"With Infilbray, we are delivering a breakthrough in care by addressing the neurological symptoms of Type 3 Gaucher disease, a milestone which reflects our deep commitment to innovation for patients and is made possible by our dedicated team who work to address their unmet medical needs."*

*"We have been able to treat the systemic manifestations of Type 3 Gaucher disease, while the neurological manifestations remained beyond the reach of available therapies," said **Dr. Pramod Mistry**, Director of the Yale Lysosomal Disease Center and Gaucher Disease Treatment Center. "The availability of a medicine capable of addressing the neurological manifestations of this devastating disorder represents a major milestone for patients, families, and the global Type 3 Gaucher disease community."*

Infilbray carries Warnings and Precautions for Suicidal Ideation and Behavior, Lens Opacification in Pediatric Patients, and Embryofoetal Toxicity. The reported adverse reactions in the primary analysis period of the LEAP2MONO study among patients receiving Infilbray (n=21) versus imiglucerase (n=22) were diarrhea (14% vs 0%), splenomegaly (14% vs 0%), nausea (14% vs 5%), depression (10% vs 0%), gastroenteritis (10% vs 0%), and vomiting (10% vs 5%).

Infilbray previously earned breakthrough therapy designation, rare pediatric disease designation, and fast-track designation in the US, as well as orphan designation for GD3 in the EU, US, and Japan. Infilbray was accepted for priority review in the US and is currently under regulatory review for GD3 in the EU, Japan and other jurisdictions worldwide. Sanofi will pursue additional global regulatory submissions for Infilbray in GD3 in 2026 and 2027.

About LEAP2MONO

The LEAP2MONO phase 3 study was a double-blinded, double-dummy, active-comparator, two-arm study that evaluated the efficacy and safety of once-daily oral Infilbray versus intravenous ERT (imiglucerase) every two weeks in adults and pediatric patients aged 12 and older with GD3. Patients must have been treated with ERT for at least three years and achieved therapeutic goals for systemic disease manifestations. Forty-three patients were randomized [1:1] to receive Infilbray and placebo infusion or ERT and placebo tablet. The primary endpoint, a global test of multiple endpoints (prespecified O'Brien ordinary least squares test) included change from baseline to week 52 in mSARA (motor function) and RBANS (cognitive function). Key systemic endpoints included spleen volume, liver volume, hemoglobin levels, and platelet count. Biomarker key secondary endpoints included percent change from baseline to week 52 in cerebrospinal fluid and plasma GL1 and lyso-GL1. The open-label phase of LEAP2MONO study is ongoing and results from its open-label phase will be presented in the future when available.

About Gaucher disease

Gaucher disease (GD) is a rare inherited lysosomal storage disease that results from a deficiency of an enzyme called glucocerebrosidase (also known as acid β-glucosidase), leading to the accumulation of molecules called glycosphingolipids (GSLs), particularly in macrophages of the spleen, liver, bone marrow, and lungs. There are three major forms within the clinical spectrum of Gaucher disease: GD1, which is characterized by the lack of primary central nervous system (CNS) involvement; GD2, which is the acute neuronopathic form; and GD3, which is the chronic neuronopathic form. In people with GD3, accumulation of GSLs in the CNS drives neuroinflammation, which can result in neurological manifestations, including cognitive deficits and difficulty with coordination and balance (ataxia), in addition to the systemic manifestations, such as liver and spleen enlargement, anemia, thrombocytopenia, and bone disease.

About Infilbray

Infilbray is a novel oral GCSi, designed to act across the blood-brain barrier, that has the potential to slow the progression of GD3 by inhibiting abnormal GSL accumulation and its

pathophysiology consequences. GSLs are cellular building blocks whose abnormal accumulation is implicated in GD3, leading to both cell dysfunction and disease progression.

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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