Press Release

Sanofi's Cenrifki (tolebrutinib) recommended for EU approval by the CHMP to treat secondary progressive multiple sclerosis without relapses

- Recommendation based on the HERCULES phase 3 study which demonstrated that brain-penetrant Cenrifki (tolebrutinib) significantly delayed the onset of disability progression in non-relapsing SPMS

Paris, April 24, 2026. The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending the approval of Cenrifki (tolebrutinib) in the EU for the treatment of secondary progressive multiple sclerosis (SPMS) without relapses in the last two years. A final decision is expected in the coming months.

SPMS is a debilitating stage of multiple sclerosis where patients experience continuous accumulation of disability, including fatigue, cognitive impairment, mobility difficulties, and loss of independence – often without available treatment options. Addressing disability progression remains one of the most significant unmet needs in MS care.

The positive CHMP opinion is based on data from the HERCULES phase 3 study (clinical study identifier: NCT04411641) in non-relapsing SPMS, with supporting data from the GEMINI 1 (clinical study identifier: NCT04410978) and GEMINI 2 (clinical study identifier: NCT04410991) phase 3 studies in relapsing multiple sclerosis (RMS), which were presented at the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) Conference 2024, the American Academy of Neurology (AAN) 2025 Annual Meeting, and published in *The New England Journal of Medicine*. The safety profile of Cenrifki has been consistent across the clinical program. Most common adverse events were COVID-19 and upper respiratory tract infections. Significant liver enzyme elevations were also observed. Drug-induced liver injury (DILI) is an identified safety risk of tolebrutinib. Strict adherence to liver monitoring requirements, and prompt management of liver enzyme elevations, are important to mitigate DILI risk.

Additional submissions for Cenrifki are currently under review with regulatory authorities worldwide.

About Cenrifki

Cenrifki (tolebrutinib) is an oral, brain-penetrant Bruton's tyrosine kinase inhibitor specifically designed to target smoldering neuroinflammation, a key driver of disability progression in MS. This mechanism addresses the underlying pathology of secondary progressive MS by targeting the inflammatory processes that contribute to disability accumulation.

Cenrifki represents Sanofi's commitment to developing innovative treatments that address the underlying causes of neurological diseases and potentially transform the treatment landscape. Standing at the intersection of neurology and immunoscience, Sanofi is focused on improving the lives of those living with serious neuroinflammatory and neurodegenerative conditions including MS, chronic inflammatory demyelinating polyneuropathy, Alzheimer's disease, Parkinson's disease, age-related macular degeneration, and other neurological diseases. The neurology pipeline currently has several projects in phase 3 studies across various diseases.

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 Statements
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