Press Release

Sanofi provides update on tolebrutinib regulatory submission in non-relapsing secondary progressive multiple sclerosis

Paris, December 24, 2025. The US Food and Drug Administration (FDA) has issued a complete response letter (CRL) for the new drug application of tolebrutinib to treat non-relapsing secondary progressive multiple sclerosis (nrSPMS) in adult patients.

On December 15, 2025, Sanofi provided an update on the ongoing review which stated that: (i) FDA was expecting the review to go beyond the previously communicated revised US target action date of December 28, 2025; (ii) further guidance from the FDA was expected by the end of the first quarter of 2026; and (iii) in response to an FDA request, Sanofi had submitted an expanded access protocol for tolebrutinib in nrSPMS. The announcement was based on the latest discussions with the FDA, which took place just before the update was provided.

> "*Today's FDA decision is a significant and meaningful change in direction from the feedback the agency previously provided to Sanofi. We are very disappointed by the FDA's action. Disability progression remains a large unmet medical need in MS, and tolebrutinib was previously awarded breakthrough therapy designation by the FDA in recognition of its potential to address this critical gap. We believe that the FDA should also take the advice of scientific experts, clinicians, and patients in this matter to ensure all perspectives are considered. We remain committed to working with the FDA to find a path forward for tolebrutinib and ultimately serve the MS community*," said **Houman Ashrafian**, Executive Vice President, Head of Research & Development at Sanofi.

Tolebrutinib was provisionally approved in the United Arab Emirates in July 2025 for the treatment of non-relapsing secondary progressive multiple sclerosis and to slow disability accumulation independent of relapse activity in adults. It is currently under regulatory review in the EU and other jurisdictions worldwide.

Financial considerations

As communicated on December 15, 2025, Sanofi is conducting an impairment test in accordance with IFRS (IAS 36) on the intangible asset value attached to tolebrutinib with a status to be provided with Q4 and FY 2025 results in January 2026. The outcome of this test will have no impact to the business net income / business EPS and there is no change to the financial guidance for 2025.

About tolebrutinib

Tolebrutinib is an investigational, 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 progressive MS by targeting the inflammatory processes that contribute to neurodegeneration and disability accumulation.

Tolebrutinib 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 neuro-inflammatory and neuro-degenerative conditions including MS, chronic inflammatory demyelinating polyneuropathy, Alzheimer's disease, Parkinson's disease, and age-related macular degeneration. The neurology pipeline

currently has several projects in phase 3 studies across various diseases.

For more information on tolebrutinib clinical studies, please visit clinicaltrials.gov.

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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