Press Release

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

- Ongoing discussions with the FDA regarding nrSPMS application have indicated regulatory decision for tolebrutinib is anticipated to be delayed

Paris, December 15, 2025. Sanofi anticipates that the review process for the ongoing US regulatory review of tolebrutinib in non-relapsing secondary progressive multiple sclerosis (nrSPMS) will extend beyond the previously communicated US target action date of December 28, 2025, and expects further guidance from the FDA by the end of the first quarter of 2026.

In response to an FDA request, Sanofi has submitted an expanded access protocol for tolebrutinib in nrSPMS, underscoring the company's commitment to providing eligible patients with access to this investigational therapy. Sanofi strongly believes in the risk-benefit profile of tolebrutinib for the treatment of nrSPMS.

About multiple sclerosis

MS is a progressive neurologic disorder characterized by accumulation of disability with shifts in the underlying biology and dominant drivers of disability over time impacting clinical presentation and treatment response.

Secondary progressive multiple sclerosis typically refers to people with a previous diagnosis of relapsing MS who have stopped experiencing relapses but continue to experience disability accumulation, in the absence of relapses.

Addressing disability accumulation remains a significant unmet need in MS, as treatment options are limited.

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.

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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