

New data for tolebrutinib, Sanofi’s investigational brain-penetrant BTK inhibitor, showed significant effect on CNS immune mediators that drive MS disease progression

- * Findings to be presented at ACTRIMS Forum 2023 showed significant impact of tolebrutinib on neuroinflammatory biomarkers in the central nervous system (CNS) associated with MS disease progression, reinforcing the potential of tolebrutinib to address disability accumulation – a significant unmet need in MS treatment
- * Additional research includes Phase 2 trial design for SAR443820, Sanofi’s investigational oral receptor-interacting protein kinase 1 (RIPK1) inhibitor

Paris, February 23, 2023. New data for tolebrutinib, Sanofi’s investigational oral Bruton’s tyrosine kinase (BTK) inhibitor for the treatment of multiple sclerosis (MS), showed a significant effect on key immune mediators that may drive disease progression within the CNS. In the study, researchers measured proteomic changes in the cerebrospinal fluid of MS patients treated with tolebrutinib, compared to patients receiving either no treatment or the B-cell depleting therapy, ocrelizumab. These findings stem from a collaborative research and development partnership with the National Institute of Neurological Disorders and Stroke (NINDS) and will be presented at the Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum 2023.

Tim Turner, PhD

Global Project Head for Tolebrutinib, Sanofi

“Delivering therapies across the tightly controlled blood-brain barrier to reach disease targets thought to be responsible for driving smoldering neuroinflammation within the central nervous system has been a tremendous hurdle in advancing innovation in multiple sclerosis. Data being presented at this year’s ACTRIMS Forum 2023 support the unique disease-modifying potential of tolebrutinib to target inflammation both in the periphery and directly in the central nervous system and, more broadly, reflect Sanofi’s long-standing commitment to advancing research that holds promise for truly transforming the way multiple sclerosis is treated.”

Additional presentations include an evaluation of the CNS penetrability of tolebrutinib in human participants at bioactive levels, as measured by drug concentration in the cerebrospinal fluid of healthy volunteers, as well as the Phase 2 MS trial design for SAR443820, Sanofi’s investigational oral RIPK1 inhibitor.

Abstracts accepted for presentation at ACTRIMS 2023 include:

Tolebrutinib	Evaluating Large Scale Proteomic Changes in Cerebrospinal Fluid of Multiple Sclerosis Patients Treated with Tolebrutinib	Poster: #P019 Feb. 23, 7:00-7:30 p.m. PST
	Tolebrutinib Demonstrates Cerebrospinal Fluid Exposure at Bioactive Levels in a Single-Ascending Dose Study in Healthy Volunteers	Poster: #P151 Feb. 23, 7:00-7:30 p.m. PST
SAR443820	Effect of RIPK1 Inhibitor, SAR443820, on Serum Neurofilament Light Chain Levels in Patients with Multiple Sclerosis: A Phase 2 Trial Design	Poster: #P072 Feb. 23, 6:30-7:00 p.m. PST

About tolebrutinib

Tolebrutinib is an investigational brain-penetrant and bioactive Bruton's tyrosine kinase (BTK) inhibitor that achieves CSF concentrations predicted to modulate B lymphocytes and microglial cells. Tolebrutinib is being evaluated in Phase 3 clinical trials for the treatment of relapsing forms of MS (RMS), non-relapsing secondary progressive MS (nrSPMS), and primary progressive MS (PPMS) and its safety and efficacy have not been evaluated by any regulatory authority worldwide. For more information on tolebrutinib clinical trials, please visit www.clinicaltrials.gov.

About Sanofi

We are an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people's lives. Our team, across some 100 countries, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible. We provide potentially life-changing treatment options and life-saving vaccine protection to millions of people globally, while putting sustainability and social responsibility at the center of our ambitions.

Sanofi is listed on Euronext: SAN and Nasdaq: SNY

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Sanofi Forward-Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the fact that product candidates if approved may not be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi's ability to benefit from external growth opportunities, to complete related transactions and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic and market conditions, cost containment initiatives and subsequent changes thereto, and the impact that COVID-19 will have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. Any material effect of COVID-19 on any of the foregoing could also adversely impact us. This situation is changing rapidly and additional impacts may arise of which we are not currently aware and may exacerbate other previously identified risks. The risks and uncertainties also include the uncertainties discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2021. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.