Media Update

Sanofi presents new data from robust MS clinical pipeline exploring multiple approaches to address important unmet patient needs

Paris, October 2, 2023. Sanofi will present new data at the 9th Joint ECTRIMS-ACTRIMS meeting evaluating three investigational treatments for multiple sclerosis (MS) that target the underlying biology of MS to treat the full spectrum of disease and reinforce the commitment to address smoldering neuroinflammation, a key driver of disability progression.

New findings from brain-penetrant and bioactive tolebrutinib, the company's potentially best-in-disease oral investigational Bruton's tyrosine kinase (BTK) inhibitor, reinforce the ability of this near-term candidate to reach the central nervous system (CNS) to target smoldering neuroinflammation at its source. Data from frexalimab, the potentially best-in-disease novel second-generation investigational anti-CD40L antibody, and SAR443820, the first-in-class oral investigational brain-penetrant receptor-interacting protein kinase 1 (RIPK1) inhibitor, will also be presented.

Erik Wallstroem, MD, PhD
Global Head of Neurology Development, Sanofi
"Our deep expertise in neuroimmunology has allowed us to explore distinct mechanisms that have the potential to halt this debilitating disease by directly crossing the blood-brain barrier or indirectly inhibiting the upstream immunological processes. Specifically for tolebrutinib, addressing the smoldering neuroinflammation activity within the CNS represents a great unmet need in MS and offers significant potential for limiting the destructive, disabling nature of this disease."

Abstracts accepted for presentation include:

Tolebrutinib (BTKi)	Safety and Clinical Efficacy Outcomes from the Long-term Extension Study of Tolebrutinib in Participants with Relapsing Multiple Sclerosis: 3-Year Results	Poster: #P278 Oct. 11, 16.30-18.30 CEST
	Bruton's Tyrosine Kinase Regulates Microglial Proinflammatory Pathways – Implications For Multiple Sclerosis	Poster: #P134 Oct. 11, 16.30-18.30 CEST
	Cerebrospinal Fluid Myeloid Modulation In Patients With Multiple Sclerosis Treated With Tolebrutinib	Oral Platform Presentation #1599 Oct. 12, 10:35-10:45 CEST
	Tolebrutinib Can Reverse a Multiple Sclerosis-Induced Cerebrospinal Fluid Proteomic Alteration	Poster: #P645 Oct. 12, 17:00–19.00 CEST
	MRI Outcomes From The Long-Term Extension Study Of Tolebrutinib in Participants With Relapsing Multiple Sclerosis: 3-Year Results	Poster: #P684 Oct. 12, 17.00–19.00 CEST
	Baseline Characteristics in the Tolebrutinib Phase 3 Non-Relapsing Secondary	Poster: #P1476 ePoster

Frexalimab (anti-CD40L)	Progressive Multiple Sclerosis (nrSPMS) HERCULES Clinical Trial	
	Phase 2 Efficacy and Safety of Frexalimab: 6 Month Results of a Novel CD40L Inhibitor in Relapsing Multiple Sclerosis	Poster: #P275 Oct. 11, 16.30-18.30 CEST
	Inhibition Of CD40L With Frexalimab Blunts Innate Immune Responses To Activated T Cells	Poster: #P1279 ePoster
SAR443820 (RIPK1i)	RIPK1 Activation Mediates Disease Progression In Multiple Sclerosis By Driving Neuroinflammatory Signaling In Microglia And Astrocytes	Poster: #P156 Oct. 11, 16.30–18.30 CEST
Disease State	Patterns and Predictors of Conversion from Relapsing-Remitting to Secondary Progressive MS: A Longitudinal Study Using the Danish Multiple Sclerosis Registry	Poster: #042 Oct. 11, 16.30–18.30 CEST
	An International Consensus with Delphi Methodology on Smoldering Disease in MS: Definition, Clinical Manifestations and Underlying Biology	Poster: #P437 Oct. 12, 17.00–19.00 CEST
	Digital Biomarkers For Early Detection Of Disability Worsening In MS: The MS-DETECT Study Design	Poster: #P1449 ePoster

About tolebrutinib

Tolebrutinib is a potentially best-in-disease oral 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 frexalimab

Frexalimab (SAR441344) is a potentially best-in-disease second generation investigational anti-CD40L antibody that blocks the costimulatory CD40/CD40L pathway which is important for activation and function of adaptive (T and B cells) and innate (macrophages/microglia and dendritic cells) immunity. Through this unique upstream mechanism of action, frexalimab has the potential to address both acute and chronic neuroinflammation in MS. Sanofi is developing SAR441344 under an exclusive license from ImmuNext Inc. Frexalimab is being evaluated in Phase 2 clinical trials for Sjogren's Syndrome, Systemic Lupus Erythematosus and Multiple Sclerosis, and its safety and efficacy have not been reviewed by any regulatory authority. For more information on frexalimab clinical trials, please visit www.clinicaltrials.gov.

About SAR443820

SAR4433820 is an oral, first-in-class brain-penetrant RIPK1 inhibitor that targets inflammatory cell signalling and activation of cell death pathways in MS pathophysiology. Its multitargeted mechanism of action and flexibility to be used as a monotherapy or in combination gives SAR443820 the potential to address neurodegeneration and disability accumulation. SAR443820

is being evaluated in Phase 2 clinical trials for Amyotrophis Lateral Sclerosis and Multiple Sclerosis, and its safety and efficacy have not been reviewed by any regulatory authority. SAR443820 is in-licensed from Denali. For more information on SAR443820 clinical trials, please visit www.clinicaltrials.gov.

For nearly two decades, we have channeled our energy into improving the lives of people with relapsing forms of MS, delivering disease-modifying therapies with distinct mechanisms of action and partnering with the MS community. We are dedicated to using our scientific and clinical heritage in MS to develop therapeutic solutions that address other neuroinflammatory, neurodegenerative, and genetic diseases.

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 pandemics or other global crises may 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. 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, 2022. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.