

New two-year efficacy and safety data for tolebrutinib, Sanofi’s investigational, brain-penetrant and bioactive BTK inhibitor, to be presented at ECTRIMS 2022

Paris, October 26, 2022. New data will be presented at the 38th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) from the long-term Phase 2b extension trial assessing two-year safety and efficacy of tolebrutinib, Sanofi’s investigational, brain-penetrant and bioactive Bruton’s tyrosine kinase (BTK) inhibitor, in patients with relapsing forms of MS, including those with highly active disease. Sanofi will also highlight findings from a large-scale proteomic analysis that provides mechanistic validation of tolebrutinib and new insight into protein alterations in MS patients, which may ultimately inform new biomarkers of disease progression to evaluate therapeutic efficacy.

Also to be presented at the congress are studies reinforcing the clinical profiles of approved MS therapies AUBAGIO® (teriflunomide) and LEMTRADA® (alemtuzumab).

Abstracts accepted for presentation at ECTRIMS include:

Tolebrutinib	Evaluating Large Scale Proteomic Changes in Cerebrospinal Fluid of Multiple Sclerosis Patients	ePoster: #EP1037 Oct. 26, 08:00 CEST
	Exploring the Utility of ActiGraph in Measuring Gait Impairment and Physical Activity in Patients with MS Using Digital Biomarkers	ePoster: #EP0885 Oct. 26, 08:00 CEST
	MRI, Efficacy, and Safety of Tolebrutinib in Patients with Highly Active Disease (HAD): 2-Year Data from the Phase 2b Long-term Safety (LTS) Study	Poster: #P292 Oct. 26, 16:30 CEST
	Safety and Clinical Efficacy Outcomes from the Long-term Extension Study of Tolebrutinib in Patients with Relapsing Multiple Sclerosis: 2-Year Results	Poster: #P308 Oct. 26, 16:30 CEST
	MRI Outcomes from the Long-term Extension Study of Tolebrutinib in Patients with Relapsing Multiple Sclerosis: 2-Year Results	Poster: #P297 Oct. 26, 16:30 CEST
	Lack of Rebound Disease Activity in Patients with Relapsing Multiple Sclerosis Following Placebo Run-out in the Tolebrutinib Phase 2b Trial	Poster: #P296 Oct. 26, 16:30 CEST

	Evaluating the Effect of a Bruton's Tyrosine Kinase Inhibitor in a Murine Experimental Autoimmune Encephalomyelitis Model of Multiple Sclerosis	Poster: #P174 Oct. 26, 16:30 CEST
	Real-world Outcomes of Teriflunomide in Relapsing-Remitting Multiple Sclerosis: A Prospective Cohort Study	ePoster: #EP1126 Oct. 26, 8:00 CEST
AUBAGIO® Teriflunomide	Teriflunomide Routine Clinical Practice in Patients with Relapsing-Remitting Multiple Sclerosis: Final Results of the TAURUS MS II Study	Poster: #P374 Oct. 26, 16:30 CEST
	Long-term Safety of Teriflunomide in Multiple Sclerosis Patients: Results of Prospective Comparative Studies in Three European Countries	Poster: #P738 Oct. 27, 17:00 CEST
LEMTRADA® Alemtuzumab	COVID-19 Severity and Vaccination Effect in Persons with MS Treated with Alemtuzumab	Poster: #P149 Oct. 26, 16:30 CEST
Franchise	Short-term Change in Disability and Processing Speed, but Not Relapse Rate, Predicts Health Related Quality of Life Five and Ten Years Later	Scientific Session #11: Quality of Life - 0104 Oct. 27, 15:35 – 15:42 CEST

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), primary progressive MS (PPMS), and myasthenia gravis (MG) 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 Aubagio® (teriflunomide)

Aubagio is approved in more than 80 countries to treat certain patients with relapsing-remitting multiple sclerosis, with additional marketing applications under review by regulatory authorities globally. Aubagio is supported by one of the largest clinical programs of any MS therapy, with more than 5,000 trial participants in 36 countries, as well as a Phase 4 study program with more than 3,600 patients currently enrolled. There is over 17 years of combined clinical and real-world experience with Aubagio. More than 114,000 patients are currently being treated with Aubagio commercially worldwide.

About Lemtrada® (alemtuzumab)

Lemtrada is approved in more than 71 countries, with additional marketing applications under review by regulatory authorities globally. Lemtrada is supported by a comprehensive and extensive clinical development program that involved nearly 1,500 patients worldwide and

>11,000 patient-years of follow-up. More than 27,000 patients have been treated with Lemtrada commercially worldwide.

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

Media Relations

Sandrine Guendoul | + 33 6 25 09 14 25 | sandrine.quendoul@sanofi.com

Sally Bain | + 1 617 834 6026 | sally.bain@sanofi.com

Kate Conway | + 1 508 364 4931 | kate.conway@sanofi.com

Investor Relations

Eva Schaefer-Jansen | + 33 7 86 80 56 39 | eva.schaefer-jansen@sanofi.com

Arnaud Delépine | + 33 6 73 69 36 93 | arnaud.delepine@sanofi.com

Corentine Driancourt | + 33 6 40 56 92 21 | corentine.driancourt@sanofi.com

Felix Lauscher | + 1 908 612 7239 | felix.lauscher@sanofi.com

Priya Nanduri | + 1 617 764 6418 | priya.nanduri@sanofi.com

Nathalie Pham | + 33 7 85 93 30 17 | nathalie.pham@sanofi.com

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.