Media Update

Patient enrollment of phase III tolebrutinib trials paused in the U.S.

Paris, June 30, 2022. The U.S. Food and Drug Administration (FDA) has placed Phase 3 studies of tolebrutinib in multiple sclerosis (MS) and myasthenia gravis on partial clinical hold. As a result, new enrollment in the United States (U.S.) is paused, and participants in the U.S. who have been in the trial for fewer than 60 days shall suspend study drug. Importantly, U.S. participants who have completed at least 60-days in the trial should continue treatment.

The FDA action was based on a limited number of cases of drug-induced liver injury that have been identified with tolebrutinib exposure in Phase 3 studies. The majority of the impacted patients were determined to have concurrent complications known historically to predispose to drug-induced liver injury. Importantly, the elevations of laboratory values used for monitoring liver injury were reversible after drug discontinuation for all cases. Following earlier dialog with FDA about these cases, study protocols were revised in May 2022 to update the monitoring frequency, and enrollment criteria were revised to exclude preexisting risk factors for hepatic dysfunction.

Enrollment in the clinical program continues with the revised study protocols and enhanced safety monitoring in countries outside of the U.S. Sanofi is working closely with the independent data monitoring committee members and investigators around the world to evaluate the effectiveness of safety measures. The program in MS has been enrolling patients since 2019 and includes more than two-thousand patients currently on tolebrutinib therapy with durations of treatment as long as 3 years.

Sanofi remains confident in the future of tolebrutinib as a potentially transformative oral treatment option for people living with MS.

About tolebrutinib

Tolebrutinib is an investigational brain-penetrant and bioactive Bruton's tyrosine kinase (BTK) inhibitor that achieves CSF concentrations needed for targeting 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 the tolebrutinib Phase III trials

GEMINI 1 (EFC16033): RMS Study of BTKi tolebrutinib
GEMINI 2 (EFC16034): RMS Study of BTKi tolebrutinib
PERSEUS (EFC16035): PPMS Study of BKTi tolebrutinib
HERCULES (EFC16645): Non-relapsing SPMS Study of BTKi tolebrutinib
URSA (EFC17262): Efficacy and Safety of Tolebrutinib in Adult Participants With Generalized Myasthenia Gravis

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.