Media Update

Tolebrutinib clinical trial program update

- Phase 3 trials in relapsing multiple sclerosis (MS), GEMINI I and GEMINI II, are fully enrolled and on track for a 2024 FDA submission in the U.S.
- Recruitment pause in progressive MS and myasthenia gravis (MG) trials in order to review previous data and the impact of the protocol changes as we work to remove the partial clinical hold in Q4 2022
- Participants who are receiving tolebrutinib in all studies will continue

Paris, August 8, 2022

The relapsing MS trials in the tolebrutinib clinical trial program, GEMINI I and GEMINI II, are now fully enrolled. Regulatory timelines for this indication remain unchanged with submission in relapsing MS expected in 2024.

This past week, following the FDA’s decision to issue a partial clinical hold for Phase 3 studies of tolebrutinib, the independent data monitoring committee (iDMC) overseeing the clinical trials recommended that all studies should pause recruitment globally. Although multiple Health Authorities outside the U.S. have permitted the tolebrutinib studies to continue following the adjustments to the protocol that reduce enrollment of patients with preexisting liver risk factors, Sanofi will respect the iDMC’s recommendation and will pause recruitment globally for those trials still undergoing active recruitment, HERCULES for non-relapsing secondary progressive MS (nrSPMS), PERSEUS for primary progressive MS (PPMS) and URSA for myasthenia gravis (MG). Sanofi’s decision is not based on any new safety findings since implementation of the FDA’s partial clinical hold at the end of June. Further, in alignment with the iDMC recommendation, all participants currently receiving tolebrutinib in all studies will continue on treatment according to the trial protocols.

John Reed, M.D., Ph.D.
Global Head of Research and Development at Sanofi

“Patient safety remains our top priority as we continue to investigate the impact of tolebrutinib on liver function during this recruitment pause. We remain confident in the future of tolebrutinib as a potentially transformative oral treatment option for people living with MS and are working closely with regulatory authorities in order to resume active recruitment within Q4 2022.”

Sanofi is committed to providing the FDA with the requested information by the end of September 2022.

About tolebrutinib
Tolebrutinib is an investigational brain-penetrant and bioactive Bruton’s tyrosine kinase (BTK) inhibitor that achieves CSF concentrations sufficient 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 the tolebrutinib Phase 3 trials
GEMINI 1 (EFC16033): RMS Study of BTKi tolebrutinib
GEMINI 2 (EFC16034): RMS Study of BTKi tolebrutinib
PERSEUS (EFC16035): PPMS Study of BTKi tolebrutinib
HERCULES (EFC16645): NRSPMS 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.