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

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