SANOFI

Press Release

Source: Sanofi (EURONEXT: SAN) (NASDAQ: SNY)

Sanofi brain-penetrant BTK inhibitor meets primary endpoint of Phase 2 trial in relapsing multiple sclerosis

- Sanofi's BTK inhibitor will potentially be first disease-modifying therapy to address sources of multiple sclerosis (MS) damage in the brain
- Sanofi to initiate four Phase 3 clinical trials in relapsing and progressive forms of MS

PARIS – February 6, 2020 – The Sanofi Phase 2b study evaluating its investigational BTK (Bruton's tyrosine kinase) inhibitor (SAR442168), an oral, brain-penetrant, selective small molecule, achieved its primary endpoint. In the trial, SAR442168 significantly reduced disease activity associated with multiple sclerosis (MS) as measured by magnetic resonance imaging (MRI). SAR442168 was well tolerated with no new safety findings.

The BTK inhibitor is thought to modulate both adaptive (B-cell activation) and innate (CNS microglial cells) immune cells linked to neuroinflammation in the brain and spinal cord.

> *"The vast majority of people living with multiple sclerosis still endure disability during the course of their disease. We believe our BTK inhibitor has the potential to transform how MS is treated. This molecule may be the first B-cell-targeted MS therapy that not only inhibits the peripheral immune system, but also crosses the blood-brain barrier to suppress immune cells that have migrated into the brain, while also modulating the brain-resident microglia cells that have been implicated in MS progression,"* said John Reed, M.D., Ph.D., Sanofi's Global Head of Research and Development. *"Building on Sanofi's heritage in multiple sclerosis, we are encouraged by these clinical results and look forward to rapidly advancing our brain-penetrant BTK inhibitor into pivotal clinical trials."*

Four Phase 3 trials will investigate the effects of SAR442168 on MS relapse rates, disability progression, and underlying central nervous system damage. Phase 3 trials in both relapsing and progressive forms of MS are planned to be initiated in the middle of this year.

In the US and Europe, there are approximately 1.2 million people diagnosed with MS, an unpredictable, chronic disease that attacks the central nervous system. Despite current treatments, many MS patients continue to accumulate disability, and one in four MS patients suffer from progressive forms of the disease with limited or no treatments available. The global market for MS therapies exceeds €20 billion annually.

Detailed results from the Phase 2b trial, including advanced imaging endpoints, will be presented at an upcoming medical meeting.

About the Phase 2b Trial

The Phase 2b trial was a randomized, double-blind, placebo-controlled, cross-over, 12-week dose-ranging trial evaluating SAR442168 in patients with recurring MS. In one group, patients (n=60) received one of four doses of SAR442168 for the first 12 weeks, then crossed over to placebo for four weeks. The other group of patients (n=60) received 4 weeks of placebo before crossing over to SAR442168, providing data that can be utilized in estimating a dose-response curve and minimizing exposure to placebo.

In the study, SAR442168 demonstrated a dose-response relationship in the reduction of new active gadolinium (Gd)-enhancing T1-hyperintense brain lesions after 12 weeks of treatment. Safety results were consistent with the previously reported Phase 1 study.

A dose-response curve for SAR442168 in terms of reduction of brain MRI lesion activity will be used for selection of the Phase 3 dose. Patients completing the week 16 visit will be eligible to enroll in a long-term safety follow-up study to assess safety and tolerability of SAR442168.

About SAR442168

SAR442168 is an investigational, oral, brain-penetrant, selective small-molecule inhibitor of BTK. SAR442168 has shown BTK binding as well as cerebrospinal fluid exposure in Phase 1 studies. The efficacy and safety of SA442168 has not been reviewed by any regulatory authority.

Sanofi obtained global rights to develop and commercialize SAR442168 under a license agreement with Principia Biopharma, Inc.

For more information on SAR442168 clinical trials, please visit www.clinicaltrials.gov.

About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

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Sanofi Forward-Looking Statements

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