Media Update

Media Update: Riliprubart one-year results from phase 2 study underpin the potential as a first-in-class treatment in chronic inflammatory demyelinating polyneuropathy

Riliprubart one-year results from phase 2 study underpin the potential as a first-in-class treatment in chronic inflammatory demyelinating polyneuropathy

- First phase 2 study to evaluate three separate participant cohorts, including those who had failed or had an inadequate response to standard-of-care (SOC) treatment and those who had not received treatment
- Riliprubart showed efficacy and safety across all enrolled cohorts, and a rapid and durable reduction of key biomarkers, including those associated with the classical complement pathway and nerve damage
- Two global CIDP phase 3 studies started recruiting

Paris, June 25, 2024. Sanofi's complement C1s inhibitor, riliprubart, showed encouraging efficacy and safety for participants with chronic inflammatory demyelinating polyneuropathy (CIDP) in the latest interim analysis from an ongoing phase 2 study. In part A results at 24 weeks, riliprubart showed promising disease-controlling benefits, with improvement or stabledisease in participants who switched from SOC to riliprubart, and improvement for participants who experienced failure or inadequate response to SOC treatment. In part B, riliprubart continued to show promising sustained benefit up to 48 weeks across all enrolled cohorts. Additional results showed that riliprubart improved participant-reported fatigue and quality-of-life measurements as well as biomarkers associated with CIDP disease progression. These data were presented at the 2024 Peripheral Nerve Society (PNS) Annual Meeting in Montreal, Canada.

Luis Querol Gutierrez, MD, PhD

Department of Neurology, Hospital de la Santa Creu i Sant Pau, Barcelona, Spain

"Many people living with CIDP do not fully respond to available therapies or do not respond at

all, demonstrating a significant unmet need for this community. These phase 2 data for riliprubart are encouraging, as they suggest that riliprubart's unique mechanism of action reduces the overactive, damaging complement pathways that may drive disease progression."

Erik Wallström, MD, PhD

Global Head of Neurology Development, Sanofi

"CIDP is a debilitating disease, often with challenging comorbidities, and nearly a third of patients experience failure to or do not adequately respond to available therapies. Our riliprubart CIDP study is the only evaluating a broad spectrum of participants, including those who experienced failure of standard-of-care therapy, as well as the first study to investigate neurofilament light chain levels as a key biomarker of CIDP progression. These results bring us hope that riliprubart may reduce disability and underlying nerve damage, further validating our ongoing CIDP phase 3 studies."

In the phase 2 study, participants with CIDP were divided into three cohorts: participants living with CIDP receiving and dependent on the current SoC treatment (SOC-treated), participants living with CIDP who experienced an inadequate response or failure to respond to at least one line of treatment (SOC-refractory) and participants who had not received a SOC treatment in the previous 6 months (SOC-naïve). Participants were initially treated with riliprubart for 24 weeks (part A), followed by an optional treatment extension for an additional year of treatment (part B).

Results from part A and B showed:

- For SOC-treated participants, 87% (42/48) improved or remained stable after switching from their previous SOC treatment to riliprubart after 24 weeks, including 52% (25/48) who experienced improvement above and beyond their previous therapy. At least 72% (29/40) remained relapse-free after approximately one year of riliprubart treatment.
- For SOC-refractory participants, 89% (16/18) improved or remained stable with riliprubart after 24 weeks, with 50% (9/18) showing improvement. 89% (8/9) sustained their response after approximately one year of riliprubart treatment.
- For SOC-naïve participants, 92% (11/12) improved or remained stable with riliprubart after 24 weeks, and at least 71% (5/7) sustained their response after approximately one year of riliprubart treatment.
- Riliprubart improved participant-reported fatigue and quality-of-life outcomes across all cohorts up to 48 weeks of treatment. The outcomes included reductions in the Rasch-built Fatigue Severity Scale and improvements in the EuroQoL Visual Analogue Scale, a health-related quality of life assessment.
- Riliprubart also reduced neurofilament light chain (NfL) levels by 35% across all three cohorts up to 48 weeks of treatment, indicating that riliprubart may reduce disease activity and the underlying nerve damage.

Riliprubart had a manageable safety profile throughout the study. Treatment-emergent adverse events (TEAEs) occurred in 64.6% (31/48) and 88.9% (16/18) of SOC-treated and SOC-refractory participants, respectively. Two deaths were reported in participants with significant medical comorbidities aside from CIDP. The most common adverse events across all cohorts (≥12%) were headache, nasopharyngitis, and COVID-19.

Sanofi has initiated two global phase 3 studies evaluating the safety and efficacy of riliprubart in adults with CIDP who experienced failure or had an inadequate response to a SOC treatment (MOBILIZE, NCT06290128) and in adults with CIDP receiving maintenance treatment with intravenous immunoglobulin (VITALIZE, NCT06290141).

CIDP is a rare neurological condition that causes progressive weakness and sensory impairment in the arms and legs. CIDP occurs when the body's immune system attacks the myelin sheaths around nerve cells in the peripheral nervous system. Timely diagnosis and treatment of CIDP is important because it allows for appropriate treatment, which is essential to preventing long-term disability. However, despite available therapies, many individuals are left with residual symptoms, including weakness, numbness, and fatigue that can lead to long-term morbidity and diminished quality-of-life. Approximately 30% of people with CIDP do not respond to standard therapies. In people with CIDP who do respond, about 70% of the response is considered incomplete. Less than one-third of participants with CIDP remain in remission without continued therapy.

About the phase 2 study

The phase 2 study is a global, multicenter, open-label study evaluating riliprubart in participants with chronic inflammatory demyelinating polyneuropathy (CIDP) across three cohorts: participants who are receiving and dependent on a SOC treatment (SOC-treated), participants who experienced failure or had an inadequate response to a SOC treatment (SOC-refractory) and participants who had not received a SOC treatment in the previous 6 months (SOC-naïve). Participants undergo 24 weeks of treatment (part A), followed by an optional treatment extension for 52 weeks (part B). In part A, the primary endpoint for the SOC-treated group is the percentage of participants who relapse after withdrawal of SOC and during the riliprubart treatment period. For the SOC-refractory and SOC-naïve groups, the part A primary endpoint is the percentage of participants responding during the riliprubart treatment period. In part B, the primary endpoint across all groups is the long-term safety and tolerability of riliprubart. Secondary endpoints include additional efficacy, safety, and tolerability measures. SOC treatment is immunoglobulins or corticosteroids.

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 the world, 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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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, 2023. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.