Press Release

Riliprubart granted orphan drug designation in Japan for chronic inflammatory demyelinating polyneuropathy

- Two phase 3 studies are currently underway testing riliprubart in people with CIDP as a potential first-in-class treatment
- Japanese Ministry of Health, Labour and Welfare decision adds to similar designations in the US and Europe, underscoring global regulatory recognition of the potential for riliprupart to address significant unmet medical needs for people living with this rare neurological condition

Paris, June 30, 2025. The Ministry of Health, Labour and Welfare (MHLW) in Japan has granted orphan drug designation to riliprubart, a monoclonal antibody that selectively inhibits activated C1s in the classical complement pathway for people with chronic inflammatory demyelinating polyneuropathy (CIDP). Despite available therapies, many CIDP patients 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. The MHLW grants orphan drug designation to medicines that address rare medical diseases or conditions with unmet medical needs. There are currently approximately 4,000 people diagnosed with CIDP in Japan.

> ***Erik Wallstroem, MD, PhD***
> Global Head of Neurology Development, Sanofi
> *"The orphan drug designation of riliprubart for people living with CIDP in Japan underscores our commitment to applying our deep understanding of the immune system to address rare neurological disorders with significant unmet medical needs. While CIDP therapies exist, many individuals continue to experience debilitating symptoms, including pain, fatigue and weakness. Our ongoing development of riliprubart reflects our dedication to challenging the status quo in neurology with the goal of improving people's lives."*

Long-term, 76-week sustained efficacy and safety data from riliprubart's phase 2 study were presented at the Peripheral Nerve Society meeting in Edinburgh, UK on May 17-20, 2025. Findings suggest a potential sustained long-term benefit provided by riliprubart across a broad spectrum of participants with CIDP. Riliprubart is currently being tested in two separate phase 3 studies: MOBILIZE in patients refractory to standard of care (clinical study identifier: NCT06290128) and VITALIZE in IVIg-treated patients (clinical study identifier: NCT06290141).

About riliprubart

SAR445088 (riliprubart) is an IgG4 humanized monoclonal antibody that selectively inhibits activated C1s in the classical complement pathway of the innate immune system. By blocking C1s, riliprubart has the potential to inhibit key inflammatory mechanisms that drive demyelination and axonal damage in CIDP. Riliprubart is currently under clinical investigation, and its safety and efficacy have not been evaluated by any regulatory authority. For more information on riliprubart clinical studies, please visit www.clinicaltrials.gov.

About CIDP

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 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 people with CIDP remain in remission without continued therapy.

About Sanofi

Sanofi is an R&D driven, AI-powered biopharma company committed to improving people's lives and delivering compelling growth. We apply our deep understanding of the immune system to invent medicines and vaccines that treat and protect millions of people around the world, with an innovative pipeline that could benefit millions more. Our team is guided by one purpose: we chase the miracles of science to improve people's lives; this inspires us to drive progress and deliver positive impact for our people and the communities we serve, by addressing the most urgent healthcare, environmental, and societal challenges of our time.

Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

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