Press Release

Riliprubart earns orphan drug designation in the US for antibody-mediated rejection in solid organ transplantation

- Ongoing phase 2 study evaluating riliprubart for the potential prevention and treatment of active antibody-mediated rejection in kidney transplant recipients
- Riliprubart was also designated orphan drug for the investigational use in chronic inflammatory demyelinating polyneuropathy in the US and EU

Paris, June 25, 2025. The US Food and Drug Administration (FDA) has granted orphan drug designation to riliprubart for the investigational treatment of antibody-mediated rejection (AMR) in solid organ transplantation. This designation reflects Sanofi's commitment to addressing a critical unmet need in transplant medicine, where AMR remains a significant challenge with no FDA-approved treatments available. The FDA grants orphan drug designation to investigational therapies addressing rare medical diseases or conditions that affect fewer than 200,000 people in the US.

> ***Alyssa Johnsen***
> Global Therapeutic Area Development Head, Immunology and Inflammation, Sanofi
> *"Orphan drug designation for riliprubart marks an important milestone in our mission to address critical challenges in transplant medicine leveraging our expertise in immunology. Antibody mediated rejection represents a serious threat to transplanted organs and patient survival. Through riliprubart's innovative mechanism of action, we hope to bring forward a treatment option that could significantly improve outcomes for kidney transplant recipients."*

Riliprubart is currently being explored in multiple clinical studies across different indications in transplant and neurology. A phase 2 clinical study is currently ongoing, exploring its potential in kidney transplant recipients (NCT05156710). The study includes two patient cohorts: those at risk of developing rejection and those with active forms of antibody-mediated rejection. In addition, Sanofi is conducting two phase 3 studies exploring riliprubart in chronic inflammatory demyelinating polyneuropathy (CIPD), a rare neurological disorder, specifically in patients refractory to standard of care (MOBILIZE, clinical study identifier: NCT06290128), and in IVIg-treated patients (VITALIZE, clinical study identifier: NCT06290141). The broad clinical development program for riliprubart emphasizes Sanofi's commitment to exploring riliprubart's potential across multiple immune-mediated conditions with high unmet medical needs.

About Riliprubart

SAR445088 (riliprubart) is a potential first-in-class, IgG4 humanized monoclonal antibody that selectively inhibits activated C1s in the classical complement pathway of the innate immune system. 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 AMR

Antibody-mediated rejection is a serious complication that may arise after solid organ transplantation, occurring when the recipient's immune system produces antibodies that attack the transplanted organ. Sensitized recipients, who have pre-existing antibodies that target foreign antigens including those found on transplanted organs, face a high risk of developing antibody-mediated rejection. Subsequent immune response can lead to inflammation, organ damage, and organ failure if left untreated.

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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