Press Release

Sanofi's rilzabrutinib earns orphan designation in the EU for IgG4-related disease

- Data from the positive Phase 2 study evaluating rilzabrutinib for the treatment of IgG4-related disease presented at EULAR 2025
- Additional orphan designation underscores Sanofi commitment to advancing new medicines in immune-mediated rare diseases

Paris, August 14, 2025. The European Medicines Agency has granted orphan designation to rilzabrutinib, a reversible covalent Bruton's tyrosine kinase (BTK) inhibitor, for IgG4-related disease (IgG4-RD). EMA grants orphan designation to investigational therapies addressing rare, life-threatening or debilitating medical diseases or conditions that affect no more than 5 in 10,000 persons in the EU.

Rilzabrutinib for the treatment of IgG4-related disease was evaluated in a phase 2 study (clinical study identifier: NCT04520451) and results were presented at the European Alliance of Associations for Rheumatology (EULAR) 2025 Congress. In IgG4-RD patients, treatment with rilzabrutinib for 52 weeks led to reduction in disease flare, other disease markers, and glucocorticoid sparing. The safety profile of rilzabrutinib in the study was consistent with previous studies, with no new safety signals observed.

In addition to IgG4-related disease, rilzabrutinib has received orphan designations for immune thrombocytopenia (ITP) in the US, the EU, and Japan; and for warm autoimmune hemolytic anemia, IgG4-RD and sickle cell disease in the US. Rilzabrutinib has also been granted fast track designation in the US in ITP and IgG4-RD.

Rilzabrutinib is currently under regulatory review in the US, the EU, and China for its potential use in ITP. The target action date for the US FDA regulatory decision for ITP, which was granted fast track designation, is August 29, 2025.

Rilzabrutinib is an investigational agent, and its safety and efficacy have not been evaluated by any regulatory authority.

About rilzabrutinib

Rilzabrutinib is a novel, advanced, oral, reversible covalent BTK inhibitor that has the potential to be an effective new medicine for several rare immune-mediated or inflammatory diseases by working to restore immune balance via multi-immune modulation. BTK, expressed in B cells, macrophages, and other innate immune cells, plays a critical role in multiple immune-mediated disease processes and inflammatory pathways. With the application of the TAILORED COVALENCY® technology, rilzabrutinib can selectively inhibit the BTK target while potentially reducing the risk of off-target side effects.

About IgG4-RD

IgG4-RD is a progressive, relapsing, chronic immune-mediated rare disease, which can manifest in almost every organ and can lead to organ damage and irreversible dysfunction with a sometimes-fatal outcome. People with IgG4-RD experience frequent flare-ups of the condition characterized by periods of exacerbated symptoms. It affects approximately eight out of 100,000 adult patients in the US each year. Due to its rarity and challenges with diagnosis, the global prevalence of IgG4-RD is unknown.

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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Sanofi forward-looking statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions, and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the fact that product candidates if approved may not be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi's ability to benefit from external growth opportunities, to complete related transactions and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic and market conditions, cost containment initiatives and subsequent changes thereto, and the impact that global crises may have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. The risks 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, 2024. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.