Press Release

Sanofi's SAR446523, a GPRC5D monoclonal antibody, earns orphan drug designation in the US for multiple myeloma

- Designation granted for IgG1-based GPRC5D monoclonal antibody for the potential treatment of patients with relapsed or refractory multiple myeloma

Paris, July 30, 2025. The US Food and Drug Administration (FDA) has granted orphan drug designation to SAR446523, an IgG1-based Antibody-Dependent Cellular Cytotoxicity-enhanced (ADCC) monoclonal antibody (mAb) targeting G-protein coupled receptor family C group 5 member D (GPRC5D) for the potential treatment of patients with relapsed or refractory multiple myeloma (R/R MM). GPRC5D is highly expressed on plasma cells in MM patients, with low expression in healthy tissues. 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.

> *"The orphan drug designation is a significant milestone in our ongoing efforts to develop innovative treatments in multiple myeloma," said **Alyssa Johnsen, MD, PhD**, Global Therapeutic Area Head, Immunology and Oncology Development at Sanofi. "This underscores our commitment to multiple myeloma, a disease for which we have acquired strong expertise with the development of another widely used and approved immunotherapy treatment."*

The safety and efficacy of SAR446523 has not been evaluated by any regulatory authority and is still under investigation.

About SAR446523

SAR446523 is an investigational IgG1-based mAb designed to target GPRC5D, which is highly expressed on plasma cells, with an engineered fragment crystallizable domain to enhance antibody dependent cell-mediated cytotoxicity. This innovative approach aims to improve the efficacy of treatment for MM, a rare and challenging cancer of plasma cells. Subcutaneous SAR446523 is currently being evaluated in an ongoing phase 1, first-in-human study in patients with R/R MM (clinical study identifier: NCT06630806). SAR4465523 originates from Sanofi Research in Vitry-sur-Seine, France.

About multiple myeloma

Multiple myeloma is considered a rare disease, yet MM is the second most common hematologic malignancy with more than 180,000 people diagnosed with MM each year, globally. Despite available treatments, MM remains an incurable malignancy with an estimated 62% five-year survival rate for newly diagnosed patients. There is a need for new frontline therapeutic options for all patients, especially for those who are transplant ineligible, due to high attrition rates in subsequent lines of therapy. Since MM does not have a cure, most patients will relapse and stop responding to therapies they have received.

At Sanofi, we are building on a long-standing commitment to oncology as we continue to chase the miracles of science to improve the lives of those living with cancer. We are committed to transforming cancer care by developing innovative, first and best-in-class immunological and targeted therapies for rare and difficult-to-treat cancers with high unmet need.

For more information on MM clinical studies, please visit www.clinicaltrials.gov.

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.