Press Release

Sarclisa approved in the EU as the first anti-CD38 therapy in combination with standard-of-care VRd to treat transplant-ineligible newly diagnosed multiple myeloma

- Approval is based on positive results from the IMROZ phase 3 study, demonstrating Sarclisa in combination with standard-of-care treatment significantly improved PFS, compared to the standard of care alone in TI NDMM
- Represents third indication in the EU, including two for the treatment of adult patients with R/R MM, and one in NDMM

Paris, January 22, 2025. Following the adoption of a positive opinion by the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP), the EU has approved Sarclisa in combination with a standard-of-care regimen, bortezomib, lenalidomide, and dexamethasone (VRd), for the treatment of adult patients with newly diagnosed multiple myeloma (NDMM) ineligible for autologous stem cell transplant (ASCT), based on data from the IMROZ phase 3 study. With the expanded marketing authorization, Sarclisa is the first anti-CD38 therapy in combination with VRd in this patient population in the EU.

Olivier Nataf
Global Head of Oncology at Sanofi
"While there have been many important advancements in multiple myeloma treatment over the past decade, there remains a significant unmet need in the front-line setting, particularly for transplant-ineligible patients. With today's decision the 27 countries in the EU will have access to a potentially transformative new combination regimen, marking a significant step forward in our mission to make a meaningful difference in multiple myeloma treatment."

In September 2024, the US Food and Drug Administration (FDA) approved Sarclisa in combination with VRd for the treatment of adult patients with NDMM who are not eligible for ASCT, representing the first global approval for Sarclisa in the front-line setting. In addition, the FDA granted orphan drug exclusivity for Sarclisa in the approved indication. Beyond the US and the EU, regulatory submissions for Sarclisa in NDMM not eligible for ASCT are under review in Japan and in China.

About Sarclisa

Sarclisa (isatuximab) is a CD38 monoclonal antibody that binds to a specific epitope on the CD38 receptor on MM cells, inducing distinct antitumor activity. It is designed to work through multiple mechanisms of action including programmed tumor cell death (apoptosis) and immunomodulatory activity. CD38 is highly and uniformly expressed on the surface of MM cells, making it a target for antibody-based therapeutics such as Sarclisa. In the US, the non-proprietary name for Sarclisa is isatuximab-irfc, with irfc as the suffix designated in accordance with nonproprietary naming of biological products guidance for industry issued by the US FDA.

Currently, Sarclisa is approved in more than 50 countries, including the US and in the EU, across three indications. Based on the ICARIA-MM phase 3 study, Sarclisa is approved in combination with pomalidomide and dexamethasone (Pd) for the treatment of patients with relapsed or refractory MM (R/R MM) who have received ≥2 prior therapies, including lenalidomide and a proteasome inhibitor, and who progressed on last therapy. Based on the IKEMA phase 3 study, Sarclisa is also approved in 50 countries in combination with carfilzomib and dexamethasone, including in the US for the treatment of patients with R/R MM who have received 1–3 prior lines of therapy and in the EU for patients with MM who have received at least 1 prior therapy. In the

US and EU, Sarclisa is approved in combination with VRd as a front-line treatment option for adult patients with NDMM, who are not eligible for ASCT, based on the IMROZ phase 3 study.

Sanofi continues to advance Sarclisa as part of a patient-centric clinical development program, which includes several phase 2 and phase 3 studies across the MM treatment continuum spanning six potential indications. In addition, the company is evaluating a subcutaneous administration method for Sarclisa in clinical studies. The safety and efficacy of Sarclisa has not been evaluated by any regulatory authority outside of its approved indications and methods of delivery.

In striving to become the number one immunoscience company globally, Sanofi remains committed to advancing oncology innovation. Through focused strategic decisions the company has reshaped and prioritized its pipeline, leveraging its expertise in immunoscience to drive progress. Efforts are centered on difficult-to-treat often rare cancers such as select hematologic malignancies and solid tumors with critical unmet needs, including multiple myeloma, acute myeloid leukemia, certain types of lymphomas, as well as gastrointestinal and lung cancers.

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

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

Media Relations

Sandrine Guendoul | + 33 6 25 09 14 25 | sandrine.guendoul@sanofi.com
Evan Berland | +1 215 432 0234 | evan.berland@sanofi.com
Nicolas Obrist | + 33 6 77 21 27 55 | nicolas.obrist@sanofi.com
Léo Le Bourhis | + 33 6 75 06 43 81 | leo.lebourhis@sanofi.com
Victor Rouault | + 33 6 70 93 71 40 | victor.rouault@sanofi.com
Timothy Gilbert | + 1 516 521 2929 | timothy.gilbert@sanofi.com

Investor Relations

Thomas Kudsk Larsen |+ 44 7545 513 693 | thomas.larsen@sanofi.com
Alizé Kaisserian | + 33 6 47 04 12 11 | alize.kaisserian@sanofi.com
Felix Lauscher | + 1 908 612 7239 | felix.lauscher@sanofi.com
Keita Browne | + 1 781 249 1766 | keita.browne@sanofi.com
Nathalie Pham | + 33 7 85 93 30 17 | nathalie.pham@sanofi.com
Tarik Elgoutni | + 1 617 710 3587 | tarik.elgoutni@sanofi.com
Thibaud Châtelet | + 33 6 80 80 89 90 | thibaud.chatelet@sanofi.com

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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 regarding the marketing and other potential of the product, or regarding potential future revenues from the product. 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, unexpected regulatory actions or delays, or government regulation generally, that could affect the availability or commercial potential of the product, the fact that product may not be commercially successful, the uncertainties inherent in research and development, including future clinical data and analysis of existing clinical data relating to the product, including post marketing, unexpected safety, quality or manufacturing issues, competition in general, risks associated with intellectual property and any related future litigation and the ultimate outcome of such litigation, and volatile economic and market conditions, and the impact that pandemics or other 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, 2023. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.