Press Release

Sanofi's Sarclisa approved in the EU for the treatment of transplant-eligible newly diagnosed multiple myeloma

- Approval based on GMMG-HD7 phase 3 study demonstrating that Sarclisa with VRd induction treatment significantly improved MRD negativity benefit and prolonged PFS compared to VRd alone
- With the first global approval in TE NDMM, Sarclisa is now approved in the EU across all lines of therapy, regardless of transplant eligibility

Paris, July 25, 2025. Following the positive opinion by the European Medicines Agency's Committee for Medicinal Products for Human Use on June 19, 2025, the European Commission has approved Sarclisa in combination with bortezomib, lenalidomide, and dexamethasone (VRd) for the induction treatment of adult patients with newly diagnosed multiple myeloma (NDMM) who are eligible for autologous stem cell transplant.

> *"We have been on a mission to accelerate Sarclisa's clinical development program with the hope to bring this important medicine to as many people as possible living with multiple myeloma," said **Olivier Nataf**, Global Head of Oncology at Sanofi. "Today's decision represents a prime example of those efforts, and most importantly, paves the way for Sarclisa to potentially become accessible to even more patients in the EU, regardless of transplant eligibility or line of therapy."*

The approval is based on results from part one of the two-part, double-randomized, German-speaking Myeloma Multicenter Group (GMMG)-HD7 phase 3 study (clinical study identifier: NCT03617731), which was designed to independently assess the effects of Sarclisa during the induction and maintenance phases. Sarclisa-VRd demonstrated a deep and rapid response in transplant-eligible (TE) NDMM patients compared to VRd alone, reflected by a statistically significant minimal residual disease (MRD) negativity benefit at the end of the 18-week induction period, which was the primary endpoint of part one.

These MRD results were supported by the final progression-free survival (PFS) analysis of part one (induction and transplant), which demonstrated a statistically significant and clinically meaningful improvement in PFS in patients treated with Sarclisa-VRd during induction, regardless of the maintenance therapy received. Additionally, the majority (53.1%) of patients receiving Sarclisa-VRd experienced continued MRD negativity (compared to 38% in the control arm), defined as MRD negativity persisting from post-induction to post-transplant, which was consistent with the prolonged PFS benefit.

The results are part of the growing body of clinical evidence supporting the use of Sarclisa in the front-line setting and reinforce the potential of Sarclisa-VRd when used prior to transplant. Data from part two, the maintenance portion of the study, are forthcoming.

With four approved indications globally, including two in the front-line setting, the approval further affirms Sarclisa as an established MM treatment option, reflecting Sanofi's ambition to address critical unmet needs in MM care and make a meaningful difference in treatment outcomes at every stage of the disease.

About the GMMG-HD7 study

GMMG-HD7 is a pivotal, randomized, open-label, multicenter, two-part phase 3 study evaluating Sarclisa in combination with VRd, also referred to as RVd (lenalidomide, bortezomib, and dexamethasone), versus VRd induction followed by post-transplant re-randomization to Sarclisa plus lenalidomide versus lenalidomide maintenance alone in TE NDMM patients. The GMMG-

initiated study is being conducted in close collaboration with Sanofi based on jointly defined research. Sanofi provided financial support to GMMG for this study. In December 2021, Sanofi and GMMG shared results from part one, which met the primary endpoint of MRD negativity after induction therapy and before transplant in NDMM patients.

The study enrolled 662 patients with TE NDMM across 67 sites in Germany. In the first part of the study, all participants were equally randomized to receive three 42-day induction cycles of VRd in both arms of the study, while Sarclisa was added to only one study arm. After induction treatment, all patients received intensification therapy with autologous stem cell transplant. In the second part of the study, patients were re-randomized post-transplant to receive Sarclisa plus lenalidomide or lenalidomide alone as maintenance therapy. During part one of the study, Sarclisa was administered through an intravenous infusion at a dose of 10 mg/kg once weekly for the first four weeks of cycle one, then every other week for the rest of the induction period.

The GMMG-HD7 protocol defined two primary endpoints: MRD negativity following induction therapy in the first part of the study, and PFS after the second randomization post-transplant in the second part, where Sarclisa was added to lenalidomide maintenance. The latter endpoint is expected to be available in due course. The key secondary endpoint for the first part of the study was PFS from first randomization. Additional secondary endpoints included rates of complete response after induction, and intensification, overall survival, and safety.

MRD negativity was assessed by next-generation flow cytometry (sensitivity of $1x10^{-5}$) after induction. In the latest results, PFS for both arms, regardless of maintenance therapy, were measured from the first randomization.

About Sarclisa

Sarclisa (isatuximab) is approved in more than 50 countries, including in the US, EU, Japan, and China, across multiple lines of treatment for MM. Based on the ICARIA-MM phase 3 study, Sarclisa is approved in the US and Japan in combination with pomalidomide and dexamethasone (Pd) for the treatment of patients with relapsed or refractory multiple myeloma (R/R MM) who have received ≥two prior therapies, including lenalidomide and a proteasome inhibitor. Additionally, Sarclisa is approved in the EU in combination with Pd for the treatment of patients with R/R MM who have received ≥two prior therapies, including lenalidomide and a proteasome inhibitor and have relapsed on the last therapy, and in China for patients who have received at least one prior line of therapy, including lenalidomide and a proteasome inhibitor. Based on the IKEMA phase 3 study, Sarclisa is also approved in more than 50 countries in combination with carfilzomib and dexamethasone, including in the US for the treatment of patients with R/R MM who have received one to three prior lines of therapy and in the EU for patients with MM who have received at least one prior therapy. In the US, EU, and China, Sarclisa is approved in combination with VRd as a front-line treatment option in transplant-ineligible NDMM patients, based on the IMROZ phase 3 study. Sarclisa is also approved in the EU in combination with VRd as an induction treatment for transplant-eligible NDMM patients, based on the GMMG-HD7 phase 3 study. In Japan, Sarclisa is approved in combination with VRd as a front-line treatment option regardless of transplant eligibility.

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 Sarclisa clinical studies, please visit www.clinicaltrials.gov.

About the German-speaking Myeloma Multicenter Group

GMMG is the largest study group focusing on MM in Germany, with headquarters based in Heidelberg. Within the last 20+ years, the GMMG study group has performed numerous studies including five randomized, multicenter phase 3 studies with 4,000 patients enrolled from about 90 participating and cotreating centers throughout Germany. The overall goal of GMMG is to generate improved therapies for myeloma patients through the development and testing of novel and personalized, genome- and signaling driven treatment strategies. The GMMG has set itself

the goal of achieving further approvals for effective antibody-based drug combinations for the first-line treatment of myeloma patients, in which antibody-based treatment regimens have been integrated into seven GMMG study concepts (CONCEPT, DANTE, DADA, HD6, HD7, HD8, HD9 and HD10).

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

Media Relations

Sandrine Guendoul | +33 6 25 09 14 25 | sandrine.guendoul@sanofi.com
Evan Berland | +1 215 432 0234 | evan.berland@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
Léa Ubaldi | +33 6 30 19 66 46 | lea.ubaldi@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
Yun Li | +33 6 84 00 90 72 | yun.li3@sanofi.com

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 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.