Press Release

Sanofi's Sarclisa subcutaneous formulation administered via on-body injector recommended for EU approval by the CHMP to treat multiple myeloma

- Recommendation based on positive results demonstrating comparable efficacy, pharmacokinetics, and safety of Sarclisa regimens administered subcutaneously compared to intravenous infusion
- If approved, Sarclisa subcutaneous (SC) would be the first available anticancer treatment to be administered through an on-body injector (OBI), and the first multiple myeloma medicine available by both SC OBI and manual injection in the EU

Paris, March 27, 2026. The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending the approval of Sarclisa (isatuximab) subcutaneous (SC) in combination with approved standard-of-care regimens for the treatment of patients with multiple myeloma (MM) across all currently approved indications for Sarclisa intravenous (IV) formulation in the EU. If approved, Sarclisa would be the first available anticancer treatment to be administered through both an on-body injector (OBI) and manual injection, and the only anti-CD38 monoclonal antibody available in MM to offer the flexibility of both an OBI and manual injection. A final decision is expected in the coming months.

> *"This positive CHMP opinion is a pivotal milestone in our mission to improve the treatment experience for multiple myeloma patients and providers,"* says **Olivier Nataf,** Global Head of Oncology at Sanofi. *"Our aim is to evolve the treatment experience by combining the clinically proven efficacy of Sarclisa with innovative subcutaneous delivery via an on-body injector. This advancement reflects our unwavering commitment to patients and dedication to transforming care in ways that truly matter to people living with cancer."*

The positive CHMP opinion is based on the results from the IRAKLIA phase 3 study in relapsed and/or refractory (R/R) MM (clinical study identifier: NCT05405166), which demonstrated non-inferiority of the SC formulation compared to the IV formulation. Four additional studies supported the decision and include the GMMG-HD8 phase 3 study in transplant-eligible newly diagnosed MM (NDMM, TE) (clinical study identifier: NCT05804032), the IZALCO phase 2 study in R/R MM (clinical study identifier: NCT05704049), and the ISASOCUT phase 2 study in transplant-ineligible NDMM (NDMM, TI) (clinical study identifier: NCT05889221) and one phase 1b study in R/R MM patients who received at least two prior lines of therapy (clinical study identifier: NCT04045795).

Of the multiple SC studies two studies showed the use of Sarclisa SC + OBI was associated with greater patient satisfaction compared to IV administration, and patient and healthcare provider preference compared to Sarclisa manual injection, based on patient experience and satisfaction questionnaires fielded in the studies.

These collective results provide comprehensive evidence supporting the potential use of Sarclisa SC + OBI to advance patient care in NDMM and R/R MM, while maintaining Sarclisa's strong efficacy and safety profile.

The studies were conducted using Enable Injections' enFuse® hands-free OBI, an automated injector designed to deliver subcutaneously high-volume medicines beginning with the push of a button, to administer Sarclisa SC formulation. The enFuse device uses a thinner and retractable needle that is smaller compared to the needles commonly used for large-volume injections, which may help support patient comfort.

Sarclisa IV is currently approved in four indications in the EU for both NDMM, TI and NDMM, TE, and as early as first relapse in R/R MM. In addition to the EU, a regulatory submission is also under review with the US Food and Drug Administration (FDA).

Sarclisa SC + OBI or manual injection is currently under clinical investigation, and its safety and efficacy have not been evaluated by any regulatory authority.

About the IRAKLIA study
IRAKLIA (clinical study identifier: NCT05405166) was a randomized, open-label, pivotal phase 3 study evaluating the non-inferiority of Sarclisa SC formulation administered at a fixed dose SC via an OBI versus weight-based dosed Sarclisa IV in combination with pomalidomide and dexamethasone (Pd) in adult patients with R/R MM who have received at least one prior line of therapy. The co-primary outcomes assessed were objective response rate (ORR), according to the 2016 International Myeloma Working Group (IMWG) criteria assessed by Independent Review Committee (IRC) and observed Sarclisa concentrations before dosing (C trough) at steady state (pre-dose at cycle 6, day 1 [C6D1]).

About the IZALCO study
IZALCO (clinical study identifier: NCT05704049) was a two-part, randomized, open-label phase 2 study evaluating the efficacy and safety of Sarclisa SC administered via the OBI or by manual injection, in combination with carfilzomib and Kd, for the treatment of adult patients with R/R MM who have received one to three prior lines of therapy. The primary objective is ORR, as assessed by IRC. The key secondary endpoint is patient preference for the Sarclisa SC administered via an OBI versus manual administration of Sarclisa SC. Healthcare provider preference of delivery method is also assessed as exploratory endpoint.

About the ISASOCUT study
ISASOCOUT (clinical study identifier: NCT05889221) is an open-label phase 2 study assessing Sarclisa SC administered via the OBI in combination with bortezomib, lenalidomide and dexamethasone (VRd) in NDMM patients ineligible for autologous stem-cell transplant (ASCT). The primary objective is rate of very good partial response (VGPR) or better, according to the 2016 IMWG criteria assessed by IRC. The study is ongoing.

About the GMMG-HD8 study
GMMG-HD8 (clinical study identifier: NCT05804032) was a randomized, open-label, multicenter phase 3 study evaluating the non-inferiority of Sarclisa SC administered via an OBI versus Sarclisa IV, both in combination with VRd at induction, for the treatment of patients with NDMM eligible for ASCT. The primary endpoint of the study is non-inferiority of SC to IV administration as measured by VGPR or better after induction therapy. Results from an interim analysis were submitted to support the conversion of the indication from Sarclisa IV to Sarclisa SC.

About Enable Injections
Cincinnati-based Enable Injections is a global healthcare innovation company committed to improving the patient treatment experience through the development and manufacturing of the enFuse® On-Body Delivery System. An innovative wearable technology, the enFuse system is designed to deliver large volumes of pharmaceutical and biologic therapeutics via subcutaneous administration, with the aim of improving convenience, supporting superior outcomes, and advancing healthcare system economics.

About Sarclisa
Sarclisa (isatuximab) is approved in more than 50 countries, including in the US, EU, Japan, and China, across multiple treatment lines for MM. Based on the ICARIA-MM phase 3 study, Sarclisa is approved in the US, and Japan 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. 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

Kd, 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 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 | +1 617 356 4751 | 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
Ekaterina Pesheva | +1 410 926 6780 | ekaterina.pescheva@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
Keita Browne | + 1 781 249 1766 | keita.browne@sanofi.com
Nathalie Pham | + 33 7 85 93 30 17 | nathalie.pham@sanofi.com
Nina Goworek | +1 908 569 7086 | nina.goworek@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 within the meaning of applicable securities laws, including 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 regarding the marketing and other potential of the product; regarding potential future events and revenues from the product. Words such as "expect," "anticipate," "believe," "intend," "estimate," "plan," "can," "contemplate," "could," "is designed to," "may," "might," "potential," "objective," "attempt," "target," "project," "strategy," "strive," "desire," "predict," "forecast," "ambition," "guideline," "seek," "should," "will," "goal," or the negative of these and similar expressions are intended to identify forward-looking statements.

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, uncertainties and assumptions 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; authorities' decisions regarding whether and when to approve a product candidate; political pressure in the United States to mandate lower drug prices including "most favored nation" pricing for State Medicaid programs; 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 pending or 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 French Markets Authority (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, 2025 or contained in our periodic reports on Form 6-K. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements. In light of these risks, uncertainties and assumptions, you should not place undue reliance on any forward-looking statements contained herein.