Press Release

Sarclisa accepted for FDA priority review for the treatment of transplant-ineligible newly diagnosed multiple myeloma

- FDA Priority Review granted based on positive results from IMROZ phase 3 study
- If approved, Sarclisa would be the first anti-CD38 therapy in combination with standard-of-care treatment for patients with newly diagnosed transplant-ineligible multiple myeloma
- Pivotal IMROZ phase 3 study results to be featured during oral presentation at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting

Paris, May 27, 2024. The U.S. Food and Drug Administration (FDA) has accepted for Priority Review the supplemental Biologics License Application (sBLA) for the investigational use of Sarclisa (isatuximab) in combination with bortezomib, lenalidomide and dexamethasone (VRd) for the treatment of patients with transplant-ineligible newly diagnosed multiple myeloma (NDMM). If approved, Sarclisa would be the first anti-CD38 therapy in combination with standard-of-care VRd in newly diagnosed patients not eligible for transplant, which would be the third indication for Sarclisa in multiple myeloma. The target action date for the FDA decision is September 27, 2024. A regulatory submission is also under review in the European Union (EU).

Dietmar Berger, M.D., Ph.D.
Chief Medical Officer, Global Head of Development at Sanofi
"Despite recent advancements in multiple myeloma treatment, there remains a significant unmet need for new frontline therapies, particularly for transplant-ineligible patients who can face poor outcomes from the disease. The filing acceptances, as well as the FDA's Priority Review designation, reinforce our confidence in Sarclisa as a potential best-in-class treatment and represent a critical step toward advancing this combination in a difficult-to-treat cancer."

The sBLA, as well as the submission in the EU, is based on positive results from the IMROZ phase 3 clinical study evaluating the investigational use of Sarclisa in combination with standard-of-care VRd. In December 2023, the study met its primary endpoint at a planned interim analysis for efficacy, demonstrating statistically significant improvement in progression-free survival (PFS) with Sarclisa in combination with VRd compared with VRd alone in transplant-ineligible patients with NDMM. The safety and tolerability of Sarclisa observed in this study was consistent with the established safety profile of Sarclisa and VRd.

The IMROZ study is the fourth phase 3 study investigating Sarclisa combinations in NDMM patients to show superiority versus standard-of-care VRd and KRd, reinforcing its best-in-class potential. Results from the IMROZ study will also be featured during an oral presentation at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting and during the plenary scientific session at the 2024 European Hematology Association (EHA) Annual Congress.

Priority Review is granted to regulatory applications seeking approval for therapies that have the potential to provide significant improvements in the treatment, diagnosis or prevention of serious conditions.

The investigational use of Sarclisa in combination with VRd in patients with transplant-ineligible NDMM is currently under clinical development, and its safety and efficacy for this indication have not been fully evaluated by any regulatory authority.

About the study

The global, randomized, multi-center, open-label IMROZ phase 3 clinical study enrolled 446 patients with newly diagnosed, transplant-ineligible MM across 21 countries and 104 centers.

During the study, Sarclisa was administered through an intravenous infusion at a dose of 10 mg/kg once weekly for five weeks during first 42-day cycle and once every two weeks in cycles 2 to 4 in combination with subcutaneous bortezomib, oral lenalidomide and intravenous or oral dexamethasone. Then Sarclisa was administered every 2 weeks from cycle 5 to 17 and every 4 weeks in cycles 18+ during 28-day cycles in combination with lenalidomide and dexamethasone at the standard dose, until disease progression, unacceptable safety profile or patient's decision to stop the study treatment.

The primary endpoint was progression-free survival. Key secondary endpoints include complete response rate, minimal residual disease (MRD) negativity rate for patients with a complete response, very good partial response or better rate, and overall survival. Other secondary endpoints were overall response rate, time to progression, duration of response, time to first response, time to best response, progression-free survival on next line of therapy, progression-free survival by MRD status, sustained MRD negativity greater than or equal to 12 months rate, safety, pharmacokinetic profile, immunogenicity, disease-specific and generic health-related quality of life, disease and treatment-related symptoms, health state utility, and health status.[1]

About Sarclisa

Sarclisa is a monoclonal antibody that binds to a specific epitope on the CD38 receptor on multiple myeloma (MM) cells, inducing distinct antitumor activity. It is designed to work through multiple mechanisms of action including programmed tumor cell death (apoptosis) and immunomodulatory activities. CD38 is highly and uniformly expressed on the surface of MM cells, making it a potential target for antibody-based therapeutics such as Sarclisa.

Based on the phase 3 ICARIA-MM study, Sarclisa is approved in >50 countries, including the U.S. and EU, in combination with pomalidomide and dexamethasone for the treatment of certain patients with relapsed refractory MM (RRMM) who have received ≥2 prior therapies, including lenalidomide and a proteasome inhibitor and who progressed on last therapy. Based on the phase 3 IKEMA study, Sarclisa is also approved in 50 countries in combination with carfilzomib and dexamethasone, including in the U.S. for the treatment of patients with RRMM who have received 1–3 prior lines of therapy and in the European Union for patients with MM who have received at least 1 prior therapy. In the U.S., the generic 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 U.S. Food and Drug Administration (FDA).

Sarclisa continues to be evaluated in multiple ongoing phase 3 clinical studies in combination with current standard treatments across the MM treatment continuum. It is also under investigation for the treatment of other hematologic malignancies, and its safety and efficacy have not been evaluated by any regulatory authority outside of its approved indication.

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

About multiple myeloma

Multiple myeloma (MM) is the second most common hematologic malignancy,[2] with more than 180,000 new diagnoses of MM worldwide yearly.[3] Despite available treatments, MM remains an incurable malignancy with an estimated 52% five-year survival rate for newly diagnosed patients.[4] Since MM does not have a cure, most patients will relapse. Relapsed MM is the term for when the cancer returns after treatment or a period of remission. Refractory MM refers to when the cancer does not respond or no longer responds to therapy.

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
Evan Berland | +1 215 432 0234 | evan.berland@sanofi.com
Nicolas Obrist | + 33 6 77 21 27 55 | nicolas.obrist@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 Larsen | +44 7545 513 693 | thomas.larsen@sanofi.com
Alizé Kaisserian | + 33 6 47 04 12 11 | alize.kaisserian@sanofi.com
Arnaud Delépine | + 33 6 73 69 36 93 | arnaud.delepine@sanofi.com
Corentine Driancourt | + 33 6 40 56 92 21 | corentine.driancourt@sanofi.com
Felix Lauscher | + 1 908 612 7239 | felix.lauscher@sanofi.com
Tarik Elgoutni | + 1 617 710 3587 | tarik.elgoutni@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 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 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.

---

[1] ClinicalTrials.gov.Identifier#NCT03319667. https://clinicaltrials.gov/ct2/show/NCT03319667. Accessed March 2024.
[2] Kazandjian D. Multiple myeloma epidemiology and survival: A unique malignancy. *Semin Oncol*. 2016;43(6):676-681. doi:10.1053/j/seminoncol.2016.11.004.
[3] World Health Organization. Multiple Myeloma. 35-multiple-myeloma-fact-sheet.pdf (who.int). Accessed March 2024.
[4] Fonseca, R., Usmani, S.Z., Mehra, M. et al. Frontline treatment patterns and attrition rates by subsequent lines of therapy in patients with newly diagnosed multiple myeloma. *BMC Cancer*. 2020: 20(1087). https://doi.org/10.1186/s12885-020-07503-y