

## *Sarclisa® (isatuximab) Phase 3 trial met primary endpoint of progression free survival in patients with newly diagnosed multiple myeloma not eligible for transplant*

- Sarclisa added to bortezomib, lenalidomide and dexamethasone (VRd) significantly reduced the risk of disease progression or death compared with VRd alone
- First global Phase 3 study to report positive results with an anti-CD38 therapy in combination with VRd in transplant-ineligible patients, reinforcing the potential for Sarclisa as a best-in-class medicine
- Study results will be submitted for presentation at an upcoming medical meeting and form the basis of a future regulatory submission

**PARIS, December 7, 2023.** The Phase 3 IMROZ trial evaluating the investigational use of Sarclisa® (isatuximab) in combination with standard-of-care bortezomib, lenalidomide and dexamethasone (VRd) met its primary endpoint at a planned interim analysis for efficacy, demonstrating statistically significant improvement in progression-free survival (PFS) compared with VRd alone in transplant-ineligible patients with newly diagnosed multiple myeloma (MM). This is also the second Phase 3 trial investigating Sarclisa in newly diagnosed patients to show superiority versus standard of care.

### ***Thierry Facon, MD***

Professor of Haematology in the Department of Haematology, Lille University Hospital, Lille, France, member of French Academy of Medicine and IMROZ Principal Investigator

*“The IMROZ trial outcome is promising for patients with newly diagnosed multiple myeloma who are transplant-ineligible, as there remains a significant unmet need for potential new therapies. First line therapeutic options are critical for all patients, but especially for those who are transplant-ineligible, given attrition rates in subsequent lines of therapy.”*

The safety and tolerability of Sarclisa observed in this trial was consistent with the established safety profile of Sarclisa and VRd.

### ***Dietmar Berger, MD, PhD***

Global Head of Development, Sanofi

*“This is the second Phase 3 trial investigating Sarclisa in newly diagnosed patients to show superiority versus standard of care, reinforcing our belief in Sarclisa as a best-in-class medicine. These data underscore our commitment to advancing scientific innovation for people living with multiple myeloma, and we look forward to sharing more detail on Sarclisa’s potential to improve outcomes for patients receiving earlier lines of therapy.”*

Study results will be submitted for presentation at an upcoming medical meeting and form the basis of a future regulatory submission.

### ***About the IMROZ trial***

The randomized, multi-center, open label Phase 3 IMROZ clinical trial enrolled 484 patients with newly diagnosed transplant-ineligible MM across 104 centers spanning 21 countries. During the trial, 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 of IMROZ is progression-free survival. Key secondary endpoints include complete response rate, minimal residual disease negativity rate for patients with a complete response, very good partial response or better rate, overall survival. Other secondary endpoints are: 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.<sup>1</sup>

The use of Sarclisa in combination with VRd in transplant-ineligible newly diagnosed MM is investigational and has not been fully evaluated by any regulatory authority.

### *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 activity. 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 patients with relapsed refractory MM (RRMM) who have received  $\geq 2$  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 trials 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 trials, please visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

### *About multiple myeloma*

MM is the second most common hematologic malignancy.<sup>2</sup> 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.

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### *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 some 100 countries, 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

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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 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, 2022. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.*

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<sup>1</sup>ClinicalTrials.gov.Identifier#NCT03319667. <https://clinicaltrials.gov/ct2/show/NCT03319667>. Accessed September 2023.

<sup>2</sup> Kazandjian. Multiple myeloma epidemiology and survival: A unique malignancy. *Semin Oncol.* 2016;43(6):676-681. doi:10.1053/j.seminoncol.2016.11.004.