Press Release

Sarclisa recommended for EU approval by the CHMP to treat transplant-ineligible newly diagnosed multiple myeloma

- Recommendation based on IMROZ phase 3 study demonstrating Sarclisa in combination with VRd significantly improved progression-free survival, compared to standard-of-care VRd alone
- If approved, Sarclisa would be the first anti-CD38 therapy in the EU available for use in combination with VRd for adult patients with transplant-ineligible NDMM

Paris, November 14, 2024. The European Medicines Agency (EMA)'s Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending the approval of Sarclisa in combination with bortezomib, lenalidomide, and dexamethasone (VRd) for the treatment of adult patients with newly diagnosed multiple myeloma (NDMM) who are ineligible for autologous stem cell transplant (ASCT). A final decision is expected in the coming months.

> ***Dietmar Berger, M.D., Ph.D.***
> Chief Medical Officer, Global Head of Development at Sanofi
> *"The positive CHMP opinion is an important step forward for people with transplant-ineligible newly diagnosed multiple myeloma for whom effective front-line therapy may improve long-term outcomes. If approved, this Sarclisa-based combination could establish a new standard-of-care treatment approach for patients in the EU, helping to address a critical care gap in multiple myeloma treatment, and reinforcing Sarclisa's potential as the anti-CD38 therapy of choice."*

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 first line setting. In addition, the FDA granted orphan drug exclusivity for Sarclisa in the approved indication.

Sarclisa is currently approved in two indications for the treatment of certain adult patients with relapsed or refractory MM in more than 50 countries, including the US and EU.

First positive global phase 3 study combining anti-CD38 therapy with VRd to significantly improve PFS versus VRd alone in transplant-ineligible NDMM supports CHMP decision

The positive CHMP opinion is based on data from the IMROZ phase 3 study, which was presented at the American Society of Clinical Oncology 2024 annual meeting, European Hematology Association 2024 meeting, and published in *The New England Journal of Medicine*. IMROZ is the first global phase 3 study of a CD38 monoclonal antibody in combination with standard-of-care VRd to significantly improve progression-free survival (PFS) versus VRd alone. The safety and tolerability of Sarclisa observed was consistent with the established safety profile of Sarclisa and VRd with no new safety signals.

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 EU, across two indications; Sarclisa is approved under an additional indication in the US. In Europe, based on

the ICARIA-MM phase 3 study, Sarclisa is approved in combination with pomalidomide and dexamethasone for the treatment of 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 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 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 US, Sarclisa is also approved in combination with VRd as a first 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 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

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