Press Release

Sarclisa is the first anti-CD38 treatment approved in China for patients with newly diagnosed multiple myeloma ineligible for transplant

- Approval based on positive results from the IMROZ phase 3 study that demonstrated Sarclisa in combination with bortezomib, lenalidomide, and dexamethasone (VRd) significantly improved progression-free survival, compared to VRd alone in transplant-ineligible newly diagnosed multiple myeloma
- Second approval in China in three weeks following the R/R MM indication announced on January 13, 2025

Paris, January 31, 2025. The National Medical Products Administration (NMPA) in China has approved Sarclisa, in combination with a standard-of-care regimen, bortezomib, lenalidomide, and dexamethasone (VRd), for the treatment of adult patients with newly diagnosed multiple myeloma (NDMM) ineligible for autologous stem cell transplant (ASCT) based on data from the IMROZ phase 3 study.

Olivier Nataf
Global Head, Oncology
"When Sanofi entered China more than four decades ago, we did so with the intention of bringing potentially transformative therapies to Chinese patients. This approval, occurring just weeks after Sarclisa's first in the country, represents tremendous progress towards advancing this mission. Now, patients with multiple myeloma and their providers have access to two new Sarclisa-based regimens that have the potential to improve outcomes across lines of therapy."

This approval closely follows the decision from the NMPA earlier in January 2025, approving Sarclisa in combination with pomalidomide and dexamethasone (Pd) for the treatment of adult patients with relapsed or refractory MM (R/R MM) who have received at least one prior line of therapy, including lenalidomide and a proteasome inhibitor. Beyond China, in the Asia-Pacific region, a regulatory submission for Sarclisa in NDMM patients not eligible for hematopoietic stem cell transplantation (HSCT) is currently under review in Japan.

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 Food and Drug Administration.

Currently, Sarclisa is approved in more than 50 countries, including in the US, EU, Japan, and China, across multiple indications. Based on the ICARIA-MM phase 3 study, Sarclisa is approved in the US, EU 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; this combination is also approved 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.

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 (SC) administration method for Sarclisa in clinical studies. In January 2024, Sanofi reported positive results from the IRAKLIA phase 3 study evaluating Sarclisa SC formulation administered via an on-body delivery system (OBDS) in combination with Pd compared to intravenous (IV) Sarclisa in patients with R/R MM. In December 2024, additional positive results from the program, including the GMMG-HD7 phase 3 study evaluating Sarclisa-RVd induction therapy in transplant-eligible NDMM patients, were also presented at the 66th American Society of Hematology Annual Meeting and Exposition. 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 often rare 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 gastroenteropancreatic neuroendocrine tumors and other 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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