Press Release

Sarclisa obtains first approval in China for the treatment of adult patients with relapsed or refractory multiple myeloma

- Approval based on positive pivotal ICARIA-MM phase 3 study using the China-based IsaFiRsT real-world study as bridging data, which demonstrated Sarclisa and the standard treatment Pd, improved responses and long-term outcomes compared to Pd alone in R/R MM patients
- Sarclisa-Pd is currently recommended by the Chinese Society of Clinical Oncology (CCSCO) and Chinese Anti-Cancer Association (CACA) treatment guidelines for this patient population

Paris, January 13, 2025. The National Medical Products Administration (NMPA) in China has approved Sarclisa, an anti-CD38 medicine, in combination with pomalidomide and dexamethasone (Pd) for the treatment of adult patients with multiple myeloma (MM) who have received at least one prior line of therapy, including lenalidomide and a proteasome inhibitor.

This approval is based on results from the pivotal ICARIA-MM phase 3 study, using the China-based IsaFiRsT real-world study as bridging data. The ICARIA-MM study demonstrated Sarclisa in combination with Pd significantly reduced the risk of disease progression or death by 40% (HR 0.596, 95% CI 0.44-0.81, p=0.001), and resulted in a clinically meaningful, 6.9-month improvement in overall survival (OS) (HR=0.78; log-rank 1-sided P=0.0319), compared to Pd alone. Additionally, the IsaFiRsT study, which is the first real-world study for the registration of an anti-CD38 therapy in combination with Pd in China, showed an overall response rate (ORR) of 82.6% among relapsed or refractory multiple myeloma (R/R MM) adult patients.

Olivier Nataf
Global Head, Oncology
"This approval marks an important milestone for Sanofi in China. The results of the ICARIA-MM phase 3 study, coupled with the real-world IsaFiRsT study, highlight the benefit of Sarclisa for patients living with multiple myeloma and the importance of innovative regulatory pathways for timely access to different treatments. We look forward to continuing to build strong partnerships with the medical community, local companies, and authorities in China as we work to bring more innovative treatments to patients."

Through the Lecheng Pilot for real-world data application, the NMPA has increasingly used real-world evidence (RWE) to help accelerate the review and approval of innovative therapies and medical devices in China. Sarclisa was one of the first three treatments authorized for real-world studies as part of the pilot program and is the first blood cancer treatment approved based on RWE, in addition to clinical data.

In addition to the NMPA approval, the Chinese Society of Clinical Oncology (CSCO) and Chinese Anti-Cancer Association (CACA) guidelines include Sarclisa-Pd as a "Category I Recommendation" and the "Preferred Option" for the treatment of patients with first-relapsed MM. Beyond R/R MM, a regulatory submission for Sarclisa in combination with bortezomib, lenalidomide and dexamethasone (VRd) for newly diagnosed multiple myeloma (NDMM) in adult patients not eligible for autologous stem cell transplant, is also under review in China with a final decision expected in the coming months.

As one of the first multinational companies to enter China in 1982, Sanofi is committed to accelerating the introduction of innovative medicines and vaccines into China, aiming to transform the practice of medicine for the benefit of more Chinese people.

About the ICARIA-MM study

ICARIA-MM was a pivotal phase 3 randomized, open-label, multi-center trial evaluating Sarclisa in combination with Pd versus Pd alone in patients with R/R MM. The study enrolled 307 patients with R/R MM across 96 centers spanning 24 countries. Overall, patients had received a median of three prior lines of anti-myeloma therapies, including at least two consecutive cycles of lenalidomide and a proteasome inhibitor given alone or in combination.

During the trial, Sarclisa was administered by intravenous infusion at a dose of 10mg/kg once weekly for four weeks, then every other week for 28-day cycles in combination with standard doses of Pd for the duration of treatment. The primary endpoint of ICARIA-MM was progression-free survival (PFS). Key secondary endpoints included ORR and OS.

About the IsaFiRsT study

The IsaFiRsT study was a single-arm, observational, prospective, real-world study evaluating Sarclisa in combination with Pd in patients with R/R MM. The study enrolled 24 patients with R/R MM at one site in China. Overall, patients received a median of three prior lines of therapy, including lenalidomide and a proteasome inhibitor, and had measurable serum or urine M-protein.

During the trial, Sarclisa was administered through an intravenous infusion at a dose of 10mg/kg once weekly for four weeks, then every other week for 28-day cycles in combination with standard doses of Pd for the duration of treatment. Treatment continued until disease progression or unacceptable toxicity. The primary endpoint of IsaFiRsT was ORR. Key secondary endpoints included PFS, OS, duration of response (DOR) and safety.

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. Based on the ICARIA-MM phase 3 study, Sarclisa is approved in combination with Pd for the treatment of patients with R/R MM 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 R/R MM who have received 1–3 prior lines of therapy and in the EU for patients with MM who have received at least 1 prior therapy. In the US, Sarclisa is approved in combination with VRd as a front-line treatment option for adult patients with NDMM not eligible for transplant based on the IMROZ phase 3 study. On November 14, 2024, the European Medicines Agency (EMA)'s Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending the approval of Sarclisa-VRd in this patient population. A final decision is expected in the coming months.

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 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 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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