

## *Sarclisa approved in Japan for patients with newly diagnosed multiple myeloma*

- Approval offers access to new treatment options for newly diagnosed MM patients
- Approval based on positive results from the IMROZ phase 3 study that demonstrated Sarclisa in combination with VRd significantly improved progression-free survival, compared to VRd alone in transplant-ineligible newly diagnosed multiple myeloma

**Paris, February 25, 2025.** The Ministry of Health, Labour and Welfare (MHLW) in Japan has approved Sarclisa, in combination with bortezomib, lenalidomide, and dexamethasone (VRd), for the treatment of adult patients with newly diagnosed multiple myeloma (NDMM) based on data from the IMROZ phase 3 study.

### ***Olivier Nataf***

Global Head, Oncology

*“In recent years, new multiple myeloma cases have increased steadily in Japan and other Asian-Pacific nations, creating a need for new treatment approaches, particularly in the front-line setting. While Sarclisa-based combinations have been approved for relapsed or refractory patients in Japan, this approval represents the first indication for certain newly diagnosed patients. We are pleased to offer physicians an important new option for their patients earlier in the treatment journey, building upon our continued commitment to advancing innovative oncology treatments in difficult-to-treat hematologic malignancies around the world.”*

In Japan, Sarclisa was launched in August 2020 and has been approved for four different treatment regimens (in combination with pomalidomide and dexamethasone, as monotherapy, in combination with carfilzomib and dexamethasone, or in combination with dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma). In addition, Sarclisa has front-line approvals in the EU and the US. In the Asia Pacific region, Sarclisa combination regimens were also [recently approved](#) by the National Medical Products Administration in China, specifically Sarclisa-VRd in NDMM patients who are not eligible for autologous stem cell transplant, as well as [Sarclisa in combination with pomalidomide and dexamethasone \(Pd\)](#) for the treatment of adult patients with relapsed or refractory MM who have received at least one prior line of therapy, including lenalidomide and a proteasome inhibitor.

### ***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  $\geq$ 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, UK, 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. This combination is also approved in Japan for patients with NDMM.

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 66<sup>th</sup> 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](http://www.clinicaltrials.gov).

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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 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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