Press Release

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

- Recommendation based on GMMG-HD7 phase 3 study demonstrating that Sarclisa with VRd induction treatment significantly improved MRD negativity benefit and prolonged PFS compared to VRd alone
- If approved, it would represent the fourth indication in the EU and second in the front-line setting globally

Paris, June 23, 2025. The European Medicines Agency'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 induction treatment of adult patients with newly diagnosed multiple myeloma (NDMM) who are eligible for autologous stem cell transplant. A final decision is expected in the coming months.

> ***Olivier Nataf***
> Global Head, Oncology
> *"The CHMP's recommendation represents significant progress toward our ambition for Sarclisa, addressing unmet patient needs in multiple myeloma care and making a meaningful difference in treatment outcomes at every stage of the disease across regions. If approved, this regimen would represent a new, important induction option for transplant-eligible patients, with the potential to improve long-term outcomes and deepen responses at a critical juncture in treatment."*

The positive CHMP opinion is based on part one results from the two-part, double-randomized, German-speaking Myeloma Multicenter Group (GMMG)-HD7 study (clinical study identifier: NCT03617731), presented at the 2024 American Society of Hematology Annual Meeting & Exposition and published in the *Journal of Clinical Oncology*.

GMMG-HD7 is the first phase 3 study to demonstrate a deep and rapid response with an anti-CD38-based induction regimen in transplant-eligible (TE) NDMM patients, with a higher proportion of patients with minimal residual disease (MRD) negativity benefit post-induction, alongside a significant progression-free survival (PFS) benefit from first randomization, regardless of maintenance therapy and without consolidation.

Additionally, the data showed the highest post-induction and post-transplant MRD negativity rates of any CD38 monoclonal antibody using VRd as a backbone in TE NDMM. The results are part of the growing body of clinical evidence supporting the use of Sarclisa in the front-line setting and reinforce the potential of Sarclisa-VRd when used prior to transplant.

Sarclisa is currently approved in three indications in the EU, across different lines of therapy in adult patients with relapsed and/or refractory (R/R) MM and with NDMM who are not eligible for transplant.

About the GMMG-HD7 study

GMMG-HD7 is an investigational pivotal, randomized, open-label, multicenter, two-part phase 3 study evaluating Sarclisa in combination with VRd, also referred to as RVd (lenalidomide, bortezomib, and dexamethasone), versus VRd induction followed by post-transplant re-randomization to Sarclisa plus lenalidomide versus lenalidomide maintenance in TE NDMM patients. The GMMG-initiated study is being conducted in close collaboration with Sanofi based on jointly defined research. Sanofi provided financial support to GMMG for this study. In December 2021, Sanofi and GMMG shared results from part one, which met the primary endpoint of MRD negativity after induction therapy and before transplant in NDMM patients.

The study enrolled 662 patients with TE NDMM across 67 sites in Germany. In the first part of the study, all participants were equally randomized to receive three 42-day cycles of VRd in both arms of the study, while Sarclisa was added to only one study arm. In the second part of the study, patients were re-randomized post-transplant to receive Sarclisa plus lenalidomide or lenalidomide alone as maintenance therapy. During the study, Sarclisa was administered through an intravenous infusion at a dose of 10 mg/kg once weekly for the first four weeks of cycle one, then every other week for the rest of the induction period.

The GMMG-HD7 protocol defined two primary endpoints: MRD negativity following induction therapy in the first part of the study, and PFS after the second randomization post-transplant in the second part, where Sarclisa was added to lenalidomide maintenance. The latter endpoint is expected to be available at a later time. The key secondary endpoint for the first part of the study was PFS from first randomization. Additional secondary endpoints included rates of complete response after induction, and intensification, overall survival, and safety.

MRD negativity was assessed by next-generation flow cytometry (sensitivity of 1x10-5) after induction. In the latest results, PFS for both arms, regardless of maintenance therapy, were measured from the first randomization.

About Sarclisa

Sarclisa (isatuximab) is approved in more than 50 countries, including in the US, EU, Japan, and China, across multiple treatment lines for MM. Based on the ICARIA-MM phase 3 study, Sarclisa is approved in the US, EU and Japan in combination with pomalidomide and dexamethasone for the treatment of patients with R/R MM who have received ≥two prior therapies, including lenalidomide and a proteasome inhibitor and have relapsed on the last therapy; 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. In Japan, Sarclisa is approved in combination with VRd as a front-line treatment option regardless of transplant eligibility.

At Sanofi, we are building on a long-standing commitment to oncology as we continue to chase the miracles of science to improve the lives of those living with cancer. We are committed to transforming cancer care by developing innovative, first and best-in-class immunological and targeted therapies for rare and difficult-to-treat cancers with high unmet need.

For more information on Sarclisa clinical studies, please visit www.clinicaltrials.gov.

About the German-speaking Myeloma Multicenter Group

GMMG is the largest study group focusing on MM in Germany, with headquarters based in Heidelberg. Within the last 20+ years, the GMMG study group has performed numerous studies including five randomized, multicenter phase 3 studies with 4,000 patients enrolled from about 90 participating and cotreating centers throughout Germany. The overall goal of GMMG is to generate improved therapies for myeloma patients through the development and testing of novel and personalized, genome- and signaling driven treatment strategies. The GMMG has set itself the goal of achieving further approvals for effective antibody-based drug combinations for the first-line treatment of myeloma patients, in which antibody-based treatment regimens have been integrated into seven GMMG study concepts (CONCEPT, DANTE, DADA, HD6, HD7, HD8, HD9 and HD10).

About Sanofi

Sanofi is an R&D driven, AI-powered biopharma company committed to improving people's lives and delivering compelling growth. We apply our deep understanding of the immune system to invent medicines and vaccines that treat and protect millions of people around the world, with an innovative pipeline that could benefit millions more. Our team is guided by one purpose: we

chase the miracles of science to improve people's lives; this inspires us to drive progress and deliver positive impact for our people and the communities we serve, by addressing the most urgent healthcare, environmental, and societal challenges of our time.
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