Press Release

Sanofi's Sarclisa subcutaneous approved in the EU as the first anticancer treatment administered via an on-body injector

- Sarclisa administered via the CirCLIQ® OBI offers a treatment experience designed around the needs of patients and HCPs and enables flexible administration in either home or outpatient settings
- Sarclisa is the first anticancer treatment to be administered through an OBI and the first MM treatment available by both SC OBI and manual injection in the EU
- Efficacy of Sarclisa demonstrated in SC formulation with innovative OBI across all indications and combinations currently approved for the IV formulation

Paris, June 8, 2026. The European Commission has approved Sarclisa (isatuximab) subcutaneous (SC) in combination with standard-of-care regimens for the treatment of patients with multiple myeloma (MM) across all existing indications for Sarclisa intravenous (IV) formulation. Sarclisa is the first anticancer therapy in the EU to be administered through an on-body injector (OBI) and manual SC administration and can provide the flexibility of administration at patients' homes and in the outpatient setting.

> *"Multiple myeloma is a complex disease that often requires repeated and prolonged clinic visits, placing a considerable burden on patients and those who support them. There has been a need for innovative approaches to ease this aspect of the treatment journey,"* said **Mohamad Mohty**, MD, PhD, Professor of Hematology at the Sorbonne University and Head of the Clinical Hematology and Cellular Therapy Department at the Saint-Antoine Hospital, Paris, France. *"The ability to administer a therapy through an on-body injector, particularly an anti-CD38 monoclonal antibody with well-established efficacy, either in the clinic or at home represents a meaningful step forward. With this new option now approved, we have an opportunity to reduce pressure on healthcare systems while placing greater flexibility and convenience at the heart of patient-centered care."*

Since launching in 2020, Sarclisa has been prescribed to patients worldwide. Sarclisa IV is currently approved across four indications in the EU, including in combination with bortezomib, lenalidomide, and dexamethasone in both transplant-ineligible newly diagnosed MM (NDMM, TI) and transplant-eligible NDMM (NDMM, TE). In relapsed and/or refractory (R/R) MM, Sarclisa is approved in combination with pomalidomide and dexamethasone (Pd) or with carfilzomib and dexamethasone. The approval of Sarclisa SC, which follows a positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use, is based on the results from the pivotal IRAKLIA phase 3 study in R/R MM (NCT05405166), which demonstrated non-inferiority of the SC formulation compared to IV, as well as additional studies.

> *"Our approach to innovation in cancer care is grounded in real-world impact, both advancing treatment and improving how care is delivered,"* said **Olivier Nataf**, Global Head of Oncology at Sanofi. *"Sarclisa, which has been prescribed to nearly 70,000 patients worldwide, already brings a well-established safety and efficacy profile across the multiple myeloma care continuum. With today's EU approval, we're combining that foundation with the added convenience, flexibility, and accessibility of the CirCLIQ on-body injector, which could offer a meaningful difference in the treatment experience."*

The IRAKLIA and IZALCO studies suggest the use of an OBI may be associated with greater simplicity, flexibility, convenience and patient satisfaction compared to IV, and that patients and healthcare providers (HCPs) prefer the OBI compared to manual SC administration. In the

IRAKLIA phase 3 study, 70% of patients treated with Sarclisa SC administered via an OBI reported being satisfied or very satisfied with their injection compared to 53.4% patients receiving Sarclisa IV (OR 2.036; 95% CI: 1.425-2.908; p=0.0001). In the IZALCO phase 2 study, after experiencing both administration methods, 74.5% of patients preferred Sarclisa SC administered via an OBI over manual injection, compared with only 17% who preferred manual injection and 8.5% with no preference (p=0.0004; binomial test against the null hypothesis of <50% rate), reinforcing strong patient preference for simplified, hands-free administration.

Sarclisa will be used in conjunction with Enable Injections' CirCLIQ® OBI, an automated injector developed using the enFuse® platform, designed to subcutaneously deliver Sarclisa with the push of a button in either outpatient or home settings. Sarclisa SC administered via the CirCLIQ® OBI uses a hidden retractable needle that is shorter and thinner compared to the needles commonly used for large-volume subcutaneous injections.

In the IRAKLIA study, the first phase 3 study to incorporate the use of an OBI in the treatment of MM, Sarclisa SC administered via an OBI in combination with Pd resulted in a 71.1% objective response rate (ORR), compared to 70.5% with Sarclisa IV-Pd, establishing non-inferiority (risk ratio [RR]: 1.008; 95% confidence interval [CI]: 0.903-1.126; p=0.0006), in adult patients with R/R MM who have received at least one prior line of treatment.

The overall safety profile of Sarclisa SC-Pd observed in this study was consistent with the established safety profile of Sarclisa IV-Pd. While 25% of patients treated with Sarclisa IV-Pd experienced systemic infusion reactions, 1.5% of patients treated with Sarclisa SC-Pd experienced those reactions. No new safety concerns were observed, except for low-grade local injection site reactions (ISRs) that occurred in .4% of OBI injections (n=19/5,145 injections). Nearly all ISRs were grade 1, except for one episode of grade 2.

The most common grade ≥3 nonhematologic adverse events (AEs) were pneumonia (14.8% OBI, 15.5% IV), COVID-19 (2.7%, 1.9%), and upper respiratory tract infection (1.5% both arms). The most common grade ≥3 hematologic laboratory abnormalities were neutropenia (84.7% OBI, 74.3% IV), thrombocytopenia (26.1%, 23%) and anemia (17.6%, 19.5%).

In patients from countries where at-home administration was permissible, median injection duration with Sarclisa SC via an OBI was the same between clinic and at-home administration (13 minutes). Home administration was well tolerated with no new safety signals and all injections were completed.

About the IRAKLIA study
IRAKLIA (clinical study identifier: NCT05405166) was a randomized, open-label, pivotal phase 3 study evaluating the non-inferiority of Sarclisa SC administered at a fixed dose SC via OBI versus weight-based dosed Sarclisa IV in combination with Pd in adult patients with R/R MM who have received at least one prior line of therapy. The co-primary outcomes assessed were ORR, defined as the proportion of patients with stringent complete response (CR), CR, very good partial response, and partial response according to the 2016 International Myeloma Working Group criteria assessed by Independent Review Committee (IRC), and observed Sarclisa SC mean concentration before dosing (Ctrough) at steady state (pre-dose at cycle 6, dose 1 [C6D1]), defined as observed Sarclisa SC plasma concentrations.

About the IZALCO study
IZALCO (clinical study identifier: NCT05704049) was a two-part randomized, open-label phase 2 study evaluating the efficacy and safety of Sarclisa SC administered via an OBI or by manual push, in combination with Kd, for the treatment of patients with R/R MM who have received one to three prior lines of therapy. The primary objective was ORR, as assessed by IRC. The secondary objectives were patient and healthcare provider preference for the OBI versus manual administration of Sarclisa SC.

About Enable Injections
Cincinnati-based Enable Injections is a global healthcare innovation company committed to improving the patient treatment experience through the development and manufacturing of the

enFuse® On-Body Delivery System. An innovative wearable technology, the enFuse system is designed to deliver large volumes of pharmaceutical and biologic therapeutics via subcutaneous administration, with the aim of improving convenience, supporting superior outcomes, and advancing healthcare system economics. For more information, visit www.enableinjections.com.

About Sarclisa
Sarclisa (isatuximab) has been approved in almost 60 countries across four indications for certain patients with NDMM and R/R MM.

Sarclisa-based regimens have been prescribed to treat nearly 70,000 patients worldwide.

Sarclisa subcutaneous is approved in the EU in combination with approved standard-of-care regimens for the treatment of patients with MM across all currently approved indications for Sarclisa IV in the EU. It is the first anticancer treatment to be administered through an OBI, and the only anti-CD38 monoclonal antibody available in MM to offer the flexibility of both SC OBI and manual injection administration. Additional regulatory submissions for Sarclisa subcutaneous are currently under review with regulatory authorities worldwide, including in the United States, China, and Japan.

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 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.
Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

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