Press Release

Sanofi's Sarclisa subcutaneous formulation approved in Japan for patients with multiple myeloma

- Approval based on multiple studies, including the pivotal IRAKLIA phase 3 study which demonstrated non-inferior efficacy and pharmacokinetics compared to Sarclisa IV
- Second global approval for Sarclisa SC following the EU

Paris, June 19, 2026. The Ministry of Health, Labour and Welfare in Japan has granted approval for Sarclisa (isatuximab) subcutaneous (SC) formulation in combination with approved standard-of-care regimens for the treatment of multiple myeloma (MM). The approved indications for Sarclisa SC in Japan include in combination with pomalidomide and dexamethasone (Pd), or with carfilzomib for the treatment of relapsed or refractory MM (R/R MM) and in combination with bortezomib, lenalidomide, and dexamethasone (VRd), for the treatment of adult patients with newly diagnosed multiple myeloma (NDMM).

A regulatory submission for the CirCLIQ on-body injector (OBI), based on the enFuse platform and submitted by Enable Injections, is under review in Japan. If approved, Sarclisa SC could become the first anticancer treatment to be administered via an OBI, and the first MM medicine in Japan to offer both manual SC injection and OBI administration.

In recent years, new MM diagnoses have increased steadily in Japan, creating a need for new treatment approaches particularly in the front-line setting. MM is the third most common hematologic malignancy in Japan.

> *"Today's approval of Sarclisa subcutaneous represents an important evolution in how we deliver care for multiple myeloma patients in Japan,"* said **Olivier Nataf**, Global Head of Oncology at Sanofi. *"This new formulation significantly eases treatment burden and enhances convenience for patients compared to intravenous administration – with the potential to become Japan's first anticancer therapy to be administered via an on-body injector."*

The approval is based on results from the IRAKLIA phase 3 study in R/R MM (clinical study identifier: NCT05405166), which demonstrated non-inferiority of the SC formulation compared to IV, as well as supportive studies. In addition to manual SC injection, these studies evaluated Sarclisa SC administered through an OBI, and were conducted using Enable Injections' enFuse hands-free OBI, an automated injector for subcutaneous delivery of Sarclisa.

In the IRAKLIA study, Sarclisa SC administered via an OBI in combination with pomalidomide and dexamethasone (Pd) resulted in a 71.1% objective response rate (ORR), compared to 70.5% with Sarclisa IV-Pd, establishing non-inferiority (risk ratio: 1.008; 95% confidence interval: 0.903-1.126; p=0.0006), in adult patients with R/R MM who had 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 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 0.4% 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 non hematologic adverse events 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 Japan, Sarclisa IV is currently approved across five indications, including in combination with VRd in NDMM, as well as four different treatment regimens in R/R MM (in combination with Pd, in combination with carfilzomib and dexamethasone (Kd), in combination with dexamethasone alone, or as a monotherapy). Sarclisa SC administered via both the CirCLIQ OBI and manual injection was approved in the EU for the treatment of MM patients across all currently approved indications and combinations for Sarclisa IV formulation in June 2026. An application for Sarclisa SC administered via both OBI and manual injection is currently under review in the US.

About the IRAKLIA study
IRAKLIA (clinical study identifier: NCT05405166) was a randomized, open-label, pivotal phase 3 study evaluating the non-inferiority of Sarclisa 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, and observed Sarclisa mean concentration before dosing (Ctrough) at steady state (pre-dose at cycle 6, dose 1 [C6D1]), defined as observed Sarclisa plasma concentrations.

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 more than 70,000 patients worldwide.

Sarclisa SC is approved in the EU and the UK in combination with approved standard-of-care regimens for the treatment of patients with MM across all currently approved indications for Sarclisa IV in these countries. 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.

Sarclisa SC is approved in Japan in combination with VRd, for the treatment of adult patients with NDMM, as well as Pd and Kd for the treatment of patients with R/R MM.

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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