Press Release

Sanofi provides update on the regulatory submission for Sarclisa subcutaneous in the US

Paris, April 22, 2026. The US Food and Drug Administration (FDA) has extended by up to three months the target action date for its review of the biologics license application for Sarclisa (isatuximab-irfc) subcutaneous (SC) in combination with approved standard-of-care regimens for the treatment of patients with multiple myeloma (MM) across all currently approved US indications of Sarclisa intravenous (IV) formulation. The revised target action date for the FDA decision is July 23, 2026.

Sanofi is committed to working closely with the FDA to bring this new advancement to patients and providers as quickly as possible. If approved, Sarclisa would be the first anticancer treatment to be administered through an on-body injector (OBI).

On March 26, 2026, the European Medicine Agency Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending the approval of Sarclisa SC administered via both an OBI and manual injection for the treatment of MM patients across all currently approved indications and combinations for Sarclisa IV formulation in the EU. A final decision is expected in the coming months.

About Sarclisa
Sarclisa (isatuximab-irfc) has been approved in almost 60 countries across four indications for certain patients with newly diagnosed MM and relapsed or refractory MM. Sarclisa-based regimens have been prescribed to treat more than 60,000 patients worldwide.

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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Sanofi forward-looking statements
This press release contains forward-looking statements within the meaning of applicable securities laws, including the Private Securities Litigation Reform Act of 1995, as amended.
Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions, and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future events and economic performance. Words such as "expect," "anticipate," "believe," "intend," "estimate," "plan," "can," "contemplate," "could," "is designed to," "may," "might," "potential," "objective," "attempt," "target," "project," "strategy," "strive," "desire," "predict," "forecast," "ambition," "guideline," "seek," "should," "will," "goal," or the negative of these, and similar expressions are intended to identify forward-looking statements.
Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the U.S Food and Drug Administration or the European Medicines Agency, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates; the fact that product candidates if approved may not be commercially successful; unexpected regulatory actions or delays, or government regulation generally; authorities' decisions regarding whether and when to approve a product candidate; political pressure in the United States to mandate lower drug prices including "most favored nation" pricing for State Medicaid programs; the future approval and commercial success of therapeutic alternatives; Sanofi's ability to benefit from external growth opportunities, to complete related transactions and/or obtain regulatory clearances, including future clinical data and analysis of existing clinical data relating to the product, including post marketing, unexpected safety, quality or manufacturing issues, competition in general; risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation; trends in exchange rates and prevailing interest rates, volatile economic and market conditions, cost containment initiatives and subsequent changes thereto, and the impact that global crises may have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. The risks and uncertainties also include the uncertainties discussed or identified in the public filings with the SEC and the French Markets Authority (AMF) made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2025 or contained in our periodic reports on Form 6-K. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements. In light of these risks, uncertainties and assumptions, you should not place undue reliance on any forward-looking statements contained herein.