

Press Release



Sanofi announces €300 million collaboration with Blackstone Life Sciences to advance an innovative treatment for multiple myeloma

- Investment will accelerate the overall Sarclisa® development program
- Sanofi will continue to fully manage the clinical program and retain full rights and control of Sarclisa® (isatuximab)

PARIS, March 15, 2022. Sanofi and Blackstone (NYSE: BX) today announced a strategic, risk-sharing collaboration under which funds managed by Blackstone Life Sciences (Bxls) will contribute up to €300 million to accelerate the global pivotal studies and the clinical development program for the subcutaneous formulation and delivery of the anti-CD38 antibody Sarclisa®, to treat patients with multiple myeloma (MM). If successful, Bxls will be eligible to receive royalties on future subcutaneous sales. The pivotal study for the subcutaneous formulation is expected to begin in the second half of 2022.

For the Sarclisa® subcutaneous formulation delivery, Sanofi has partnered with drug delivery technology innovator company [Enable Injections](#), Inc. to advance the development of a subcutaneous delivery for Sarclisa® with the goal of offering a unique patient-centric treatment experience.

To-date, Sarclisa® has received regulatory approval for intravenous administration to treat certain patients with relapsed MM and is under investigation across the MM treatment continuum of care for other hematologic malignancies and solid tumors.

John Reed, MD, Ph.D.

Global Head of Research and Development for Sanofi

“The collaboration with Blackstone will accelerate our ability to offer patients a subcutaneous anti-CD38 antibody therapy that we believe will be innovative and more convenient. We are committed to building an industry-leading, sustainable pipeline with a steady stream of new therapies that have the potential to transform the practice of medicine.”

Nicholas Galakatos, Ph.D.

Global Head of Blackstone Life Sciences

“We are excited to collaborate with Sanofi’s experienced development team to advance a subcutaneous dosage form for Sarclisa for patients. Our investment demonstrates Blackstone’s commitment and ability to provide innovative sources of financing to the world’s leading pharmaceutical companies as we offer capital at scale and complementary expertise to help advance important medicines in critical therapeutic areas.”

Sanofi has considerable expertise in oncology and has increased research and development capabilities, focusing on difficult to treat cancers, including breast, blood, and lung.

Additional terms of the collaboration were not disclosed.

About Sarclisa®

Sarclisa® is a monoclonal antibody that targets a specific epitope on the CD38 receptor on MM cells. 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 potential target for antibody-based therapeutics such as Sarclisa®.

Based on the Phase 3 ICARIA-MM study, Sarclisa® is approved in a number of countries in combination with pomalidomide and dexamethasone for the treatment of patients with relapsed refractory MM (RRMM) who have received ≥ 2 prior therapies, including lenalidomide and a proteasome inhibitor. Based on the Phase 3 IKEMA study, Sarclisa® is also approved in combination with carfilzomib and dexamethasone in the U.S. for the treatment of patients with RRMM who have received 1–3 prior lines of therapy and in the European Union for patients with MM who have received at least 1 prior therapy. In the U.S., the generic 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 U.S. Food and Drug Administration (FDA).

Sarclisa® continues to be evaluated in multiple ongoing Phase 3 clinical trials in combination with current standard treatments across the MM treatment continuum. It is also under investigation for the treatment of other hematologic malignancies and solid tumors. The safety and efficacy of these additional uses have not been reviewed by any regulatory authority worldwide.

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

About Multiple Myeloma

Multiple myeloma (MM) is the second most common hematologic malignancy,¹ with more than 130,000 new global annual diagnoses². Despite available treatments, MM remains an incurable malignancy and is associated with significant patient burden. Since MM does not have a cure, most patients will relapse. Relapsed MM is the term for when the cancer returns after treatment or a period of remission. Refractory MM refers to when the cancer does not respond or no longer responds to therapy.

About Blackstone Life Sciences

Blackstone Life Sciences is an industry-leading private investment platform with capabilities to invest across the life cycle of companies and products within the key life science sectors. By combining scale investments and hands-on operational leadership, Blackstone Life Sciences helps bring to market promising new medicines and medical technologies that improve patients' lives. More information is provided at <https://www.blackstone.com/our-businesses/life-sciences/>.

About Sanofi

¹ Kazandjian. Multiple myeloma epidemiology and survival: A unique malignancy. *Semin Oncol*. 2016;43(6):676-681. doi:10.1053/j/semioncol.2016.11.004.

² International Myeloma Foundation. Myeloma Action Month. <https://mam.myeloma.org/learn-more-about-multiple-myeloma/>. Accessed December 2021.

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 some 100 countries, 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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Sanofi Forward-Looking Statements

This press release contains forward-looking statements as defined in 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 performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. 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 FDA or the EMA, 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, 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, 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 COVID-19 will 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. Any material effect of COVID-19 on any of the foregoing could also adversely impact us. This situation is changing rapidly and additional impacts may arise of which we are not currently aware and may exacerbate other previously identified risks. The risks and uncertainties also include the uncertainties discussed or identified in the public filings with the SEC and the 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, 2021. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.