

European Commission approves Sarclisa[®] (isatuximab) for adults with relapsed and refractory multiple myeloma

- * EC approval based on data from first randomized Phase 3 trial (ICARIA-MM) to report results evaluating an anti-CD38 monoclonal antibody combined with pomalidomide and dexamethasone (pom-dex)
- * Sarclisa in combination with pom-dex significantly reduced the risk of progression or death by 40% versus pom-dex alone
- * Multiple myeloma is the second most common blood cancer, with approximately 40,000 new cases per year in Europe

PARIS – June 2, 2020 – The European Commission (EC) has approved Sarclisa[®] (isatuximab) in combination with pomalidomide and dexamethasone (pom-dex) for the treatment of adult patients with relapsed and refractory multiple myeloma (MM) who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on the last therapy.

Sarclisa is a monoclonal antibody (mAb) that binds to a specific epitope on the CD38 receptor of MM cells.

“The EC approval of Sarclisa represents an important additional therapeutic option and may set a new standard of care for myeloma patients in Europe who are in need of new effective treatments because their disease has returned or they have become refractory to their previous treatment,” said John Reed, M.D., Ph.D., Global Head of Research and Development at Sanofi. *“Sarclisa in combination with pom-dex demonstrated median progression-free survival of nearly one year, a five-month improvement over pom-dex alone, in patients who had already failed at least two prior therapies.”*

Sarclisa Efficacy and Safety Profile in Difficult-to-Treat Patients

In the Phase 3 ICARIA-MM study, Sarclisa added to pom-dex (Sarclisa combination therapy, n=154) demonstrated a statistically significant improvement of progression-free survival (PFS), with a median PFS of 11.53 months compared to 6.47 months with pom-dex alone (n=153) (HR 0.596, 95% CI: 0.44-0.81, p=0.001). Sarclisa combination therapy also demonstrated a significantly greater overall response rate compared to pom-dex alone (60.4% vs. 35.3%, p<0.0001). In additional analyses, Sarclisa combination therapy compared to pom-dex alone showed a treatment benefit consistent across select subgroups reflective of real-world practice, including patients with high risk cytogenetics, those aged 75 years and older, patients with renal insufficiency and patients who were refractory to lenalidomide.

“As patients experience relapse of their multiple myeloma or become refractory to their current therapy, they become more difficult to treat with increasingly poor prognoses. In the ICARIA-MM trial, Sarclisa combination therapy showed a treatment benefit consistent across relapsed and refractory multiple myeloma subgroups,” said Philippe Moreau, M.D., Department of Hematology, University Hospital of Nantes, France. *“Sarclisa offers an important new treatment option and a potentially new standard of care for these patients with relapsed, refractory disease.”*

As outlined in the Summary of Product Characteristics (SmPC), the most frequent adverse reactions observed with Sarclisa (occurring in 20% or more of patients) are neutropenia (46.7%), infusion reactions (38.2%), pneumonia (30.9%), upper respiratory tract infection (28.3%), diarrhea (25.7%) and bronchitis (23.7%). The most frequent serious adverse reactions are pneumonia (9.9%) and febrile neutropenia (6.6%).

For more information on the safety of Sarclisa, please refer to the SmPC.

An Important New Option for Treating Multiple Myeloma

Sarclisa is administered by intravenous (IV) administration and is dosed at 10 mg/kg, in combination with pom-dex, every week for four weeks and then every two weeks, until disease progression or unacceptable toxicity. Assuming no rate adjustments based on infusion-related reactions, the first infusion takes three to four hours, the second infusion takes less than two hours, and the remaining infusions can decrease to 75 minutes from the third infusion onwards. A treatment cycle is 28 days. The EC marketing authorization for Sarclisa is applicable to the 27 member states of the European Union (EU), plus the UK, Iceland, Liechtenstein and Norway.

Multiple Myeloma: A Significant Burden to Patients

MM is the second most common hematologic malignancy,¹ with more than 138,000 new cases worldwide each year.² In Europe, approximately 40,000 patients are diagnosed with MM yearly.³ MM remains incurable in the vast majority of patients, resulting in significant disease burden.

About Sarclisa

Sarclisa is a mAb that binds to a specific epitope on the CD38 receptor. CD38 is highly and uniformly expressed on MM cells, making it a potential target for antibody-based therapeutics such as Sarclisa. It is designed to induce programmed tumor cell death (apoptosis) and immunomodulatory activity.

In addition to the EU, Sarclisa has also been approved in the U.S., Switzerland, Canada and Australia in combination with pom-dex for the treatment of certain adults with relapsed refractory MM. 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.

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.

About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

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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, 2019. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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

² International Myeloma Foundation. Myeloma Action Month. <http://mam.myeloma.org/educate/>. Accessed January 2019. 2/6.

³ João C, Costa C, Coelho I, Vergueiro MJ, Ferreira M, Silva MG. Long-term survival in multiple myeloma. *Clinical Case Reports.* 2014;2(5):173-179. doi:10.1002/ccr3.76. 3. Schey SA, Morris J, Maguire Á, Dhanasiri