

Sanofi receives positive CHMP opinion for Sarclisa® (isatuximab) for the treatment of relapsed and refractory multiple myeloma

- * Positive CHMP opinion based on data from ICARIA-MM, the first randomized Phase 3 trial to evaluate an anti-CD38 in combination with pom-dex
- * Sarclisa in combination with pomalidomide and dexamethasone (pom-dex) significantly reduced the risk of disease progression or death in adults by 40% compared to pom-dex alone in the trial
- * Sarclisa was approved by the FDA on March 2 in combination with pom-dex for the treatment of certain adults with RRMM
- * Multiple myeloma remains an incurable cancer associated with significant patient burden and need for additional treatments

Paris – March 27, 2020 – The European Medicines Agency’s Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for Sarclisa® (isatuximab). The CHMP recommends Sarclisa 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.

The European Commission (EC) will review the CHMP recommendation and a final decision on the Marketing Authorisation Application for Sarclisa in the E.U. is expected in the coming months. Sarclisa has not been approved for commercial use in the E.U. Sarclisa was approved in the US on March 2 in combination with pomalidomide and dexamethasone (pom-dex) for the treatment of adults with RRMM who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.

“Relapsed and refractory multiple myeloma is a complicated disease that continuously develops resistance to treatment, creating a significant need for continued innovation,” said John Reed, M.D., Ph.D., Sanofi’s Global Head of Research & Development. *“This positive CHMP opinion for Sarclisa brings us closer to our ambition to deliver a new treatment option for patients in Europe with relapsed and refractory multiple myeloma.”*

Sarclisa Phase 3 Study Results in Patients with RRMM

The CHMP positive opinion is based on data from ICARIA-MM, the first randomized Phase 3 trial to evaluate an anti-CD38 monoclonal antibody (mAB) in combination with pom-dex. In the 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=0.0010). 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.

The most common adverse reactions (all grades occurring in 20% or more of patients) in patients who received Sarclisa combination therapy were neutropenia (96%), infusion-related reactions (39%), pneumonia (31%), upper respiratory tract infection (57%) and diarrhea (26%). Serious adverse reactions that occurred in more than 5% of patients who received Sarclisa combination therapy included pneumonia (25.3%) and febrile neutropenia (12.3%). Permanent discontinuation of Sarclisa combination therapy due to an adverse reaction (Grades 3-4) occurred in 7% of patients, and 3% of patients discontinued due to an infusion-related reaction.

Multiple Myeloma: A Significant Burden to Patients

Multiple myeloma is the second most common hematologic malignancy¹, with more than 138,000 new diagnoses of multiple myeloma worldwide yearly.² In Europe, approximately 39,000 patients are diagnosed with multiple myeloma each year.³ Despite available treatments, multiple myeloma remains an incurable malignancy, and is associated with significant patient burden. Since multiple myeloma does not have a cure, most patients will relapse. Relapsed multiple myeloma is the term for when the cancer returns after treatment or a period of remission. Refractory multiple myeloma refers to when the cancer does not respond or no longer responds to therapy.

About Sarclisa

CD38 is highly and uniformly expressed on multiple myeloma cells and cell surface receptors, making it a potential target for antibody-based therapeutics such as Sarclisa. Sarclisa is a monoclonal antibody that binds to a specific epitope on the CD38 receptor on multiple myeloma cells. It is designed to work through many mechanisms of action including programmed tumor cell death (apoptosis) and immunomodulatory activity. The clinical significance of these findings is under investigation.

Sarclisa is approved in the U.S. in combination with pom-dex for the treatment of adults with relapsed refractory multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor. 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.

Outside of the U.S., Sarclisa is an investigational agent and its safety and efficacy have not been established by any regulatory authority worldwide.

Sarclisa continues to be evaluated in multiple ongoing Phase 3 clinical trials in combination with current standard treatments across the multiple myeloma 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, the impact of global disruptions, including pandemics, cost containment initiatives and subsequent changes thereto, the average number of shares outstanding as well as those 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