

## FDA approves Sarclisa<sup>®</sup> (isatuximab-irfc) for patients with relapsed refractory multiple myeloma

- \* Sarclisa in combination with pomalidomide and dexamethasone (pom-dex) significantly reduced the risk of disease progression or death by 40% compared to pom-dex alone in a pivotal trial
- \* FDA approval based on data from the only randomized Phase 3 trial (ICARIA-MM) to evaluate an anti-CD38 in combination with pom-dex that has presented results to date
- \* Multiple myeloma is the second most common blood cancer, affecting more than 130,000 patients in the U.S.; approximately 32,000 Americans are diagnosed with multiple myeloma each year

**PARIS – March 2, 2020** – The U.S. Food and Drug Administration (FDA) has approved Sarclisa<sup>®</sup> (isatuximab-irfc) in combination with pomalidomide and dexamethasone (pom-dex) for the treatment of adults with relapsed refractory multiple myeloma (RRMM) who have received at least two prior therapies including lenalidomide and a proteasome inhibitor. Sarclisa is expected to be available to patients in the U.S. shortly.

Sarclisa is a monoclonal antibody that binds to the CD38 receptor on multiple myeloma cells.

*“Today’s FDA approval of Sarclisa provides a new treatment option for patients with difficult-to-treat multiple myeloma. These are patients whose disease has returned or become resistant to their prior treatments,”* said Paul Hudson, Chief Executive Officer, Sanofi. *“At Sanofi, we are focused on discovering and developing medicines that may change the practice of medicine, and Sarclisa offers a potential new standard of care in the United States. We continue to evaluate Sarclisa in a comprehensive clinical program in multiple myeloma, as well as in other blood cancers and solid tumors.”*

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

In the ICARIA-MM study, Sarclisa added to pom-dex (Sarclisa combination therapy) demonstrated a statistically significant improvement in progression free survival (PFS) with a median PFS of 11.53 months compared to 6.47 months with pom-dex alone (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).

*“Most patients with multiple myeloma unfortunately relapse and become refractory to currently available therapies. Sarclisa used in combination with pomalidomide and dexamethasone offers an important new treatment option for patients in the United States living with this incurable disease,”* said Paul Richardson, MD, principal investigator of ICARIA-MM, and clinical program leader and director of clinical research at the Jerome Lipper Multiple Myeloma Center at Dana-Farber Cancer Institute. *“The pivotal ICARIA-MM trial was the first Phase 3 study of a CD38 antibody in combination with pom-dex to present results demonstrating significant clinical benefit in this setting. The study enrolled a broad population of patients with relapsed and refractory multiple myeloma that is particularly difficult to treat and with poor prognosis, which is reflective of real-world practice.”*

The most common adverse reactions (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.

### **An Important New Option for Treating Multiple Myeloma**

Sarclisa offers an 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. The first cycle is administered in an infusion time of 200 minutes, which can decrease to 75 minutes for the third cycle onwards. A treatment cycle is 28 days.

The U.S. list price (wholesale acquisition cost, or WAC) for Sarclisa is \$650 per 100 mg vial and \$3,250 per 500 mg vial. For a typical patient in the U.S., between 70-80 kg (154-176 lbs), this correlates to a cost of \$5,200 per infusion. Actual costs to patients are generally anticipated to be lower as the list price does not reflect insurance coverage, copay support, or financial assistance from patient support programs. Sanofi is committed to responsible pricing while bringing innovative and valuable therapies to patients with significant unmet need.

Patients in the U.S. who have been prescribed Sarclisa may be eligible to enroll in the CareASSIST Patient Support Program, which provides reimbursement support and financial assistance to eligible patients. For more information, please call 1-833-WE+CARE (1-833-930-2273) or visit [SanofiCareAssist.com/Sarclisa](http://SanofiCareAssist.com/Sarclisa).

### **Multiple Myeloma Leads to Significant Disease Burden**

Multiple myeloma is the second most common hematologic malignancy,<sup>1</sup> affecting more than 130,000 patients in the United States; approximately 32,000 Americans<sup>2</sup> are diagnosed with multiple myeloma each year. Despite available treatments, multiple

myeloma remains an incurable malignancy, and is associated with significant patient burden. As patients relapse, they can become refractory to therapies they have received. There is a need for new agents so that patients and physicians can have options as the disease progresses over time. Relapsed (or recurrent) multiple myeloma means that the cancer returns after treatment or a period of remission. Since multiple myeloma does not have a cure, most patients will relapse at some point. Refractory multiple myeloma refers to cancer that does not respond to therapy.

## About Sarclisa

Sarclisa is a monoclonal antibody (mAb) that binds to the CD38 receptor on multiple myeloma cells. It is designed to induce programmed tumor cell death (apoptosis) and immunomodulatory activity. 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 has Orphan Drug Designation status from the FDA and the European Medicines Agency (EMA). In the second quarter of 2019, the EMA accepted for review the Marketing Authorization Application for use of Sarclisa in combination with pom-dex for the treatment of certain patients with RRMM. The safety and efficacy of Sarclisa has not been fully evaluated by any regulatory authority outside of the U.S.

Sarclisa continues to be evaluated in multiple ongoing Phase 3 clinical trials in combination with current standard treatments for people with relapsed refractory or newly diagnosed multiple myeloma. It is also under investigation for the treatment of other blood cancer types (hematologic malignancies) and solid tumors.

## 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 regarding the marketing and other potential of the product, or regarding potential future revenues from the product. 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, unexpected regulatory actions or delays, or government regulation generally, that could affect the availability or commercial potential of the product, the absence of guarantee that the product will be commercially successful, the uncertainties inherent in research and development, 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 future litigation and the ultimate outcome of such litigation, and volatile economic conditions, as well as those risks 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, 2018. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.*

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

<sup>2</sup> National Cancer Institute. Myeloma Cancer Stat Facts. Available at: [www.seer.cancer.gov/statfacts/html/mulmy.html](http://www.seer.cancer.gov/statfacts/html/mulmy.html). Accessed on December 12, 2019.