

## *Sarclisa® (isatuximab) combination provides unprecedented median progression free survival in patients with relapsed multiple myeloma receiving a proteasome inhibitor therapy*

- Latest results of the Phase 3 IKEMA trial demonstrate the longest median progression free survival (mPFS) on a proteasome inhibitor backbone in patients who relapsed after a prior therapy, including lenalidomide
- The median progression free survival, increased from 19.2 months to 35.7 months when Sarclisa was added to carfilzomib and dexamethasone
- Further analysis, following U.S. Food and Drug Administration recommendations on censoring rules, showed mPFS increased from 20.8 to 41.7 months when Sarclisa was added to carfilzomib and dexamethasone

**PARIS, May 15, 2022.** Latest results from the Phase 3 IKEMA clinical trial evaluating Sarclisa® (isatuximab) in combination with carfilzomib and dexamethasone (Kd) demonstrated a median progression free survival (mPFS) of 35.7 months (Hazard Ratio [HR] 0.58; 95% Confidence Interval [CI]: 25.8 to 44.0; n=179), compared to 19.2 months in patients treated with Kd alone (95% CI: 15.8 to 25.1; n=123), as evaluated by an Independent Review Committee. These results, presented at the Controversies in Multiple Myeloma World Congress, represent the longest mPFS among studies investigating a proteasome inhibitor backbone in the second-line setting for the treatment of relapsed multiple myeloma (MM). These data will also be presented at the European Society for Medical Oncology on May 19.

### ***Philippe Moreau, MD***

Head of the Department of Hematology, University Hospital of Nantes, France

*“The increase in progression free survival, observed consistently across all subgroups, when adding Sarclisa to carfilzomib and dexamethasone is remarkable in patients with relapsed multiple myeloma in a proteasome inhibitor combination. Relapse is common in multiple myeloma, creating the need for differentiated second-line treatments that provide patients a longer period of time without disease progression. This updated analysis reinforces the potential for Sarclisa to become a new standard of care for patients with relapsed multiple myeloma.”*

A PFS analysis following the U.S. Food and Drug Administration recommendations on censoring rules, as applied in the approved U.S. prescribing information, showed an mPFS of 41.7 months for Sarclisa added to Kd (Sarclisa combination therapy) compared to 20.8 months in patients treated with Kd alone (HR 0.59; 95% CI: 27.1 to Not Calculable [NC]).

Time to next treatment for patients treated with Sarclisa combination therapy was 44.9 months (HR 0.55; 95% CI: 31.6 to NC) versus those treated with Kd alone at 25 months (95% CI: 17.9 to 31.3). Time to next treatment measured the interval from the date of randomization<sup>1</sup> to the date of commencement of the next line of therapy, thereby allowing for measurement of the period of therapeutic benefit.<sup>2</sup>

### ***Peter C. Adamson, MD***

Global Head of Oncology Clinical Development and Pediatric Innovation at Sanofi

*“To observe progression free survival of more than three years in patients with relapsed multiple myeloma when Sarclisa was added to a proteasome inhibitor backbone of therapy is unprecedented and reinforces our confidence in Sarclisa as a potential best in class anti-CD38 antibody.”*

The safety and tolerability of Sarclisa observed in this analysis were consistent with the safety profile of Sarclisa in other clinical trials, with no new safety signals observed. For the Sarclisa combination therapy and Kd groups, the most common adverse events were infusion related reaction (45.8%, 3.3%), diarrhea (39.5%, 32%), hypertension (37.9%, 35.2%), upper respiratory tract infection (37.3%, 27%), fatigue (31.6%, 20.5%), dyspnoea (30.5%, 22.1%), pneumonia (27.1%, 21.3%), back pain (25.4%, 21.3%), insomnia (25.4%, 24.6%), and bronchitis (24.3%, 12.3%). Treatment exposure in the Sarclisa combination therapy arm was 30 weeks longer than in the control arm. Treatment emergent adverse events (TEAEs) of  $\geq$  Grade 3 were reported in 83.6% of patients treated with Sarclisa combination therapy and in 73% of those treated with Kd alone. Serious TEAEs were higher in the Sarclisa combination therapy arm versus Kd alone (70.1% versus 59.8%). No difference was observed after exposure adjustment.”

These results will be discussed with regulatory authorities at a future date.

### *About the IKEMA trial*

The randomized, multi-center, open label Phase 3 IKEMA clinical trial enrolled 302 patients with relapsed MM across 69 centers spanning 16 countries. All study participants had received one to three prior anti-myeloma therapies. During the trial, Sarclisa was administered through an intravenous infusion at a dose of 10mg/kg once weekly for four weeks, then every other week for 28-day cycles in combination with carfilzomib twice weekly at the 20/56mg/m<sup>2</sup> dose and dexamethasone at the standard dose for the duration of treatment. The primary endpoint of IKEMA was progression free survival. Secondary endpoints included overall response rate, the rate of complete response or better, the rate of very good partial response or better, rate of minimal residual disease-negativity, overall survival and safety.<sup>3</sup>

### *About Sarclisa*

Sarclisa is a monoclonal antibody that targets a specific epitope on the CD38 receptor on multiple myeloma (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, including the U.S. and EU, in combination with pomalidomide and dexamethasone for the treatment of patients with relapsed refractory MM (RRMM) who have received  $\geq 2$  prior therapies, including lenalidomide and a proteasome inhibitor. Based on the Phase 3 IKEMA study, Sarclisa is also approved in multiple countries in combination with carfilzomib and dexamethasone, including 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](http://www.clinicaltrials.gov).

### *About multiple myeloma*

MM is the second most common hematologic malignancy,<sup>4</sup> with more than 130,000 new diagnoses of MM worldwide yearly.<sup>5</sup> 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.

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### About Sanofi

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.

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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.

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<sup>1</sup> ClinicalTrials.gov. Identifier # NCT03275285.

<https://www.clinicaltrials.gov/ct2/show/NCT03275285?term=IKEMA&draw=2&rank=1>. Accessed April 2022.

<sup>2</sup> Campbell. Time to Next Treatment as a Meaningful Endpoint for Trials of Primary Cutaneous Lymphoma. *Cancers* vol. 12,8 2311. 17 Aug. 2020, doi:10.3390/cancers12082311.

<sup>3</sup> ClinicalTrials.gov. Identifier # NCT03275285.

<https://www.clinicaltrials.gov/ct2/show/NCT03275285?cond=NCT03275285&draw=2&rank=1>. Accessed April 2022.

<sup>4</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>5</sup> International Myeloma Foundation. Myeloma Action Month. <https://mam.myeloma.org/learn-more-about-multiple-myeloma/>. Accessed April 2022.