

Sarclisa® (isatuximab) Phase 3 IKEMA trial meets primary endpoint early in patients with relapsed multiple myeloma

- * IKEMA trial results released early based on recommendation of an Independent Data Monitoring Committee
- * Addition of Sarclisa significantly reduced the risk of disease progression or death compared to carfilzomib and dexamethasone alone
- * Results will be submitted to an upcoming medical meeting and form the basis for regulatory submissions later this year

PARIS – May 12, 2020 - The Phase 3 IKEMA clinical trial evaluating Sarclisa® (isatuximab) added to carfilzomib and dexamethasone met the primary endpoint at its first planned interim analysis, demonstrating significantly prolonged progression-free survival compared to standard of care carfilzomib and dexamethasone alone in patients with relapsed multiple myeloma. There were no new safety signals identified in this study.

“When Sarclisa was added to standard-of-care treatment carfilzomib and dexamethasone in this phase 3 trial, results clearly demonstrated a significant reduction in risk of disease progression or death,” said John Reed, M.D., Ph.D., Global Head of Research and Development at Sanofi. *“This is the second positive phase 3 trial for Sarclisa, further supporting the potential our medicine has to improve outcomes for patients struggling with relapsed multiple myeloma.”*

Results will be submitted to an upcoming medical meeting and are anticipated to form the basis of regulatory submissions planned for later this year.

About the Trial

The randomized, multi-center, open label Phase 3 IKEMA clinical trial enrolled 302 patients with relapsed multiple myeloma across 69 centers spanning 16 countries. All study participants 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/m² dose and dexamethasone at the standard dose for the duration of treatment. The primary endpoint of IKEMA is progression-free survival. Secondary endpoints include overall response rate, the rate of very good partial response or greater, minimal residual disease, complete response rate, overall survival and safety.

The use of Sarclisa in combination with carfilzomib and dexamethasone in relapsed multiple myeloma is investigational and has not been fully evaluated by any regulatory authority.

About 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. CD38 is highly and uniformly expressed on the surface of multiple myeloma cells, making it a potential target for antibody-based therapeutics such as Sarclisa.

Sarclisa is approved in the U.S. in combination with pomalidomide and dexamethasone 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.

Sarclisa has also received positive CHMP opinion in combination with pomalidomide and dexamethasone for the treatment of adults with relapsed and refractory multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on the last therapy. A final decision on the Marketing Authorisation Application for Sarclisa in the E.U. is expected in the coming months. The safety and efficacy of Sarclisa has not been fully evaluated by any regulatory authority outside of the U.S., Switzerland, Canada and Australia.

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

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

About Multiple Myeloma

Multiple myeloma is the second most common hematologic malignancy, with more than 138,000 new diagnoses of multiple myeloma worldwide yearly. 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 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.

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