FDA Approves New Sarclisa Regimen for Multiple Myeloma

The monoclonal antibody reduces the risk of disease progression or death by 45%.

April 20, 2021 By Food and Drug Administration (FDA)

On March 31, 2021, the Food and Drug Administration approved isatuximab-irfc (Sarclisa, Sanofi-Aventis U.S. LLC) in combination with carfilzomib (Kyprolis) and dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy.

The efficacy and safety of isatuximab-irfc in combination with carfilzomib and dexamethasone was evaluated in IKEMA (NCT03275285), a multicenter, multinational, randomized, open-label, two-arm, Phase III trial in patients with relapsed and/or refractory multiple myeloma who had received one to three prior lines of therapy. The trial randomized 302 patients (3:2) to receive isatuximab-irfc with carfilzomib and dexamethasone (Isa-Kd) or carfilzomib and dexamethasone (Kd).

The main efficacy outcome measure was progression-free survival (PFS), assessed by an independent response committee based on central laboratory data for M-protein and central radiologic imaging review using International Myeloma Working Group criteria.

Median PFS was not reached in the Isa-Kd arm and was 20.27 months (95% CI: 15.77-NR) in the Kd arm (HR 0.548; 95% CI: 0.366-0.822; p=0.0032), representing a 45% reduction in the risk of disease progression or death in patients treated with Isa-Kd compared to those treated with Kd.

The most common adverse reactions (≥20%) in patients receiving isatuximab with carfilzomib and dexamethasone were upper respiratory tract infection, infusion-related reactions, fatigue, hypertension, diarrhea, pneumonia, dyspnea, insomnia, bronchitis, cough, and back pain. The most common hematology laboratory abnormalities (≥80%) were decreased hemoglobin, decreased lymphocytes, and decreased platelets.

The recommended isatuximab-irfc dose with carfilzomib and dexamethasone is 10 mg/kg as an intravenous infusion every week for 4 weeks followed by every 2 weeks until disease progression or unacceptable toxicity.

View full prescribing information for Sarclisa.

This review used the Assessment Aid, a voluntary submission from the applicant to facilitate the

FDA’s assessment. The FDA approved this application 3 months ahead of the FDA goal date.

Isatuximab has orphan drug designation for the treatment of multiple myeloma. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA’s MedWatch Reporting System or by calling 1-800-FDA-1088.

This announcement was originally published on the Food and Drug Administration website on March 31, 2021.
