Sarclisa® (isatuximab-irfc) – New indication

- On September 20, 2024, Sanofi announced the FDA approval of Sarclisa (isatuximab-irfc), in combination with bortezomib, lenalidomide, and dexamethasone, for the treatment of adult patients with newly diagnosed multiple myeloma who are not eligible for autologous stem cell transplant (ASCT).

- Sarclisa is also approved in combination with:

    — Pomalidomide and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least 2 prior therapies including lenalidomide and a proteasome inhibitor
    — Carfilzomib and dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received 1 to 3 prior lines of therapy.

- The approval of Sarclisa for the new indication was based on IMROZ, a randomized, open-label study in 446 patients with newly diagnosed multiple myeloma who were not eligible for stem cell transplantation. Patients were randomized to either Sarclisa in combination with bortezomib, lenalidomide, and dexamethasone (Isa-VRd) or bortezomib, lenalidomide, and dexamethasone (VRd). The primary endpoint was progression-free survival (PFS).

    — Median PFS was not reached in the Isa-VRd arm vs. 54.34 months in the VRd arm (hazard ratio 0.60, 95% CI: 0.44, 0.81; p = 0.0009).

- The most common adverse reactions (≥ 20%) with Sarclisa use for its new indication were upper respiratory tract infections, diarrhea, fatigue, peripheral sensory neuropathy, pneumonia, musculoskeletal pain, cataract, constipation, peripheral edema, rash, infusion-related reaction, insomnia, and COVID-19. The most common hematologic laboratory abnormalities (≥ 80%) were decreased hemoglobin, decreased leukocytes, decreased lymphocytes, decreased platelets, and decreased neutrophils.

- The recommended dose of Sarclisa is 10 mg/kg actual body weight administered as an intravenous infusion. The dosing schedule when used in combination with bortezomib, lenalidomide, and dexamethasone is:

    — Cycle 1 (42-day cycle): days 1, 8, 15, 22, and 29
    — Cycle 2 to 4 (42-day cycle): days 1, 15, and 29 (every 2 weeks)
    — Cycles 5 to 17 (28-day cycle): days 1 and 15 (every 2 weeks)
    — Cycles 18 and beyond (28-day cycles): day 1 (every 4 weeks).

- Refer to the Sarclisa drug label for the dosing schedule for its other indications.