Sarclisa® (isatuximab-irfc) – New indication

- On March 31, 2021, Sanofi announced the FDA approval of Sarclisa (isatuximab-irfc), in combination with Kyprolis® (carfilzomib) and dexamethasone, for the treatment of relapsed or refractory multiple myeloma in adult patients who have received one to three prior lines of therapy.

- Sarclisa is also approved in combination with Pomalyst® (pomalidomide) and dexamethasone, for the treatment of multiple myeloma in adult patients who have received at least two prior therapies including Revlimid® (lenalidomide) and a proteasome inhibitor.

- Multiple myeloma is a form of blood cancer that occurs in infection-fighting plasma cells found in the bone marrow. Relapsed multiple myeloma is when the cancer returns after treatment or a period of remission. Refractory multiple myeloma refers to when the cancer no longer responds to therapy.

- The approval of Sarclisa for the new indication was based on data from the IKEMA study, a randomized, open-label study in 302 patients with relapsed and/or refractory multiple myeloma. Patients were randomized to receive either Sarclisa in combination with Kyprolis and dexamethasone (Isa-Kd) or Kyprolis and dexamethasone (Kd) alone. The efficacy of Sarclisa was based upon progression-free survival (PFS).

    - Isa-Kd combination therapy reduced the risk of disease progression or death by 45% vs. Kd alone (hazard ratio 0.548, 95% CI: 0.366 to 0.822, p = 0.0032).
    - Isa-Kd combination therapy did not demonstrate a statistically significant improvement in overall response rate compared to Kd alone (86.6% vs. 82.9%, p = 0.3859).

- The most common adverse reactions (≥ 20%) with Sarclisa use in combination with Kd were upper respiratory tract infections, infusion-related reactions, fatigue, hypertension, diarrhea, pneumonia, dyspnea, insomnia, bronchitis, cough, and back pain. The most common hematology laboratory abnormalities (≥ 80%) were anemia, lymphopenia, and thrombocytopenia.

- The recommended dose of Sarclisa is 10 mg/kg actual body weight administered as an intravenous infusion in combination with Pomalyst and dexamethasone or in combination with Kyprolis and dexamethasone. In cycle 1, Sarclisa should be administered on days 1, 8, 15, and 22 (weekly). In cycle 2 and beyond, Sarclisa should be administered on days 1 and 15 (every 2 weeks). Treatment is repeated until disease progression or unacceptable toxicity.

    - Premedications should be administered prior to Sarclisa infusion to reduce the risk and severity of infusion-related reactions.
    - Sarclisa should be administered by a healthcare professional, with immediate access to emergency equipment and appropriate medical support to manage infusion-related reactions if they occur.