Sarclisa® (isatuximab-irfc) – New orphan drug approval

- On March 2, 2020, the FDA announced the approval of Sanofi's Sarclisa (isatuximab-irfc), in combination with Pomalyst® (pomalidomide) and dexamethasone, for the treatment of adult patients with multiple myeloma 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. The disease may result in a weakened immune system and cause other bone or kidney problems. The National Cancer Institute estimates there would be 32,270 new cases of multiple myeloma and 12,830 related deaths in the U.S. in 2020.

- Sarclisa is a monoclonal antibody that binds to the CD38 receptor on multiple myeloma cells. It is designed to induce programmed tumor cell death and immunomodulatory activity.

- The efficacy of Sarclisa was established in a randomized, open-label study in 307 patients with relapsed and refractory multiple myeloma. Patients were randomized to receive either Sarclisa in combination with pomalidomide and low-dose dexamethasone (PomDex) or pomalidomide and low-dose dexamethasone (PomDex). The primary endpoint was progression-free survival (PFS).

    - Sarclisa plus PomDex demonstrated a statistically significant improvement in PFS with a median PFS of 11.53 months (95% CI: 8.94, 13.9) vs. 6.47 months (95% CI: 4.47, 8.28) with PomDex alone (hazard ratio 0.596, 95% CI: 0.44 to 0.81, p = 0.0010).
    - Sarclisa combination therapy also demonstrated a significantly greater overall response rate compared to PomDex alone (60.4% vs. 35.3%; p < 0.0001).

- Warnings and precautions for Sarclisa include infusion-related reactions, neutropenia, second primary malignancies, laboratory test interference, and embryo-fetal toxicity.

- The most common adverse reactions (≥ 20%) with Sarclisa use were neutropenia, infusion-related reactions, pneumonia, upper respiratory tract infection, and diarrhea. The most common hematology laboratory abnormalities (≥ 80%) were anemia, neutropenia, lymphopenia, and thrombocytopenia.

- The recommended dose of Sarclisa is 10 mg/kg actual body weight administered as an intravenous infusion in combination with pomalidomide and dexamethasone. In cycle 1, the dosing schedule for Sarclisa is on days 1, 8, 15, and 22 (weekly). In cycles 2 and beyond, the dosing schedule for Sarclisa is on days 1, 15 (every 2 weeks).

    - Each treatment cycle consists of a 28-day period. Treatment is repeated until disease progression or unacceptable toxicity.
    - 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.
    - Refer to the Sarclisa drug label for information regarding pre-infusion medication administration.

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- Sanofi plans to launch Sarclisa shortly. Sarclisa will be available as 100 mg/5 mL (20 mg/mL) and 500 mg/25 mL (20 mg/mL) solution in single-dose vials.