Rolvedon™ (eflapegrastim-xnst) – New drug approval

- On September 9, 2022, Spectrum Pharmaceuticals announced the FDA approval of Rolvedon (eflapegrastim-xnst), to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia.
    - Rolvedon is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.
- Rolvedon is a long-acting granulocyte colony-stimulating factor (G-CSF).
- The efficacy of Rolvedon was established in a two randomized, open-label, active-controlled non-inferiority studies of similar design (Study 1 and Study 2) in a total of 643 patients with early-stage breast cancer receiving myelosuppressive anti-cancer drugs. Patients were randomized to receive Rolvedon or pegfilgrastim, another G-CSF. The primary endpoint for both studies was based on the duration of severe neutropenia (DSN) in cycle 1.
    - In both studies, Rolvedon was non-inferior to pegfilgrastim.
    - In study 1, the mean DSN was 0.20 days for Rolvedon and 0.35 days for pegfilgrastim (difference -0.148, 95% CI: -0.265, -0.033).
    - In study 2, the mean DSN was 0.31 days for Rolvedon and 0.39 days for pegfilgrastim (difference -0.073, 95% CI: -0.292, 0.129).
- Warnings and precautions for Rolvedon include splenic rupture; acute respiratory distress syndrome; serious allergic reactions; sickle cell crisis in patients with sickle cell disorders; glomerulonephritis; leukocytosis; thrombocytopenia; capillary leak syndrome; potential for tumor growth stimulatory effects on malignant cells; myelodysplastic syndrome and acute myeloid leukemia in patients with breast and lung cancer; aortitis; and nuclear imaging.
- The most common adverse reactions (≥ 20%) with Rolvedon use were fatigue, nausea, diarrhea, bone pain, headache, pyrexia, anemia, rash, myalgia, arthralgia, and back pain.
- The recommended dosage of Rolvedon is a single subcutaneous injection of 13.2 mg administered once per chemotherapy cycle. Rolvedon should be administered approximately 24 hours after cytotoxic chemotherapy. It should not be administered within the period from 14 days before to 24 hours after administration of cytotoxic chemotherapy.
    - Rolvedon is administered by a healthcare professional.
- Spectrum Pharmaceuticals plans to launch Rolvedon in the fourth quarter of 2022. Rolvedon will be available as a 13.2 mg/0.6 mL solution in a single-dose prefilled syringe.