Zynyz™ (retifanlimab-dlwr) – New drug approval

- On March 22, 2023, Incyte announced the FDA approval of Zynyz (retifanlimab-dlwr), for the treatment of adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC).
    - This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
- MCC is a rare and aggressive type of skin cancer. MCC tends to grow quickly and has a high rate of metastatic disease, leading to a poor prognosis.
    - MCC impacts less than 1 per 100,000 people in the U.S.
- Zynyz is a programmed death receptor-1 (PD-1)–blocking antibody.
- The efficacy of Zynyz was established in POD1UM-201, an open-label, single-arm study in 65 patients with metastatic or recurrent locally advanced MCC who had not received prior systemic therapy for their advanced disease. Patients received Zynyz every 4 weeks until disease progression, unacceptable toxicity, or up to 24 months. The major efficacy outcomes were objective response rate (ORR) and duration of response (DOR).
    - The ORR was 52% (95% CI: 40, 65).
    - The median DOR was 1.1 to 24.9+ months.
- Warnings and precautions for Zynyz include severe and fatal immune-mediated adverse reactions; infusion-related reactions; complications of allogeneic hematopoietic stem cell transplantation (HSCT); and embryo-fetal toxicity.
- The most common adverse reactions (≥ 10%) with Zynyz use were fatigue, musculoskeletal pain, pruritus, diarrhea, rash, pyrexia, and nausea.
- The recommended dosage of Zynyz is 500 mg administered as an intravenous infusion over 30 minutes every 4 weeks until disease progression, unacceptable toxicity, or up to 24 months.
- Incyte's launch plans for Zynyz are pending. Zynyz will be available as a 500 mg/20 mL (25 mg/mL) solution in a single-dose vial.