Tazverik™ (tazemetostat) – New orphan drug approval

- On January 23, 2020, the FDA announced the approval of Epizyme's Tazverik (tazemetostat), for the treatment of adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection.
    - This indication is approved under accelerated approval based on overall response rate and duration of response.
    - Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

- Epithelioid sarcoma is a rare sub-type of soft tissue sarcoma that often occurs in young adults. Most cases of epithelioid sarcoma begin in the soft tissue under the skin of an extremity. Surgical removal is considered the main treatment when the cancer is localized to one area of the body. Chemotherapy or radiation may also be given. However, there is a high likelihood for local and regional spread of the disease even with treatment and approximately 50% of patients have metastatic disease at the time of diagnosis.

- Tazverik is the first EZH2 inhibitor and the first approved product for the treatment of epithelioid sarcoma.

- The efficacy of Tazverik was evaluated in an open-label, single-arm cohort of a study in 62 patients with metastatic or locally advanced epithelioid sarcoma. Patients received Tazverik until disease progression or unacceptable toxicity. The major efficacy outcome measures were confirmed overall response rate (ORR) and duration of response (DOR). The median duration of follow-up was 14 months (range 0.4 to 31).
    - The ORR was 15% (95% CI: 7, 26).
    - The percentage of patients with a DOR of at least 6 months was 67%. The range in the DOR was 3.7 to 24.5+ months.

- Warnings and precautions for Tazverik include secondary malignancies and embryo-fetal toxicity.

- The most common adverse reactions (≥ 20%) with Tazverik use were pain, fatigue, nausea, decreased appetite, vomiting, and constipation.

- The recommended dose of Tazverik is 800 mg orally twice daily with or without food until disease progression or unacceptable toxicity.

- Epizyme plans to launch Tazverik within 10 business days. Tazverik will be available as a 200 mg tablet.

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