Tazverik™ (tazemetostat) – New indications

- On June 18, 2020, Epizyme announced the FDA approval of Tazverik (tazemetostat), for the treatment of adult patients with relapsed or refractory (R/R) follicular lymphoma (FL) whose tumors are positive for an enhancer of zeste homolog 2 (EZH2) mutation as detected by an FDA-approved test and who have received at least 2 prior systemic therapies, and adult patients with R/R FL who have no satisfactory alternative treatment options.
    - These indications are approved under accelerated approval based on overall response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
- Tazverik is also approved 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.
- The efficacy of Tazverik was evaluated in two open-label, single-arm cohorts of a study in 95 patients with histologically confirmed FL after at least 2 prior systemic therapies. Patients received Tazverik until confirmed disease progression or unacceptable toxicity. The major efficacy outcome measures were overall response rate (ORR) and duration of response (DOR).
    - The ORR was 69% (95% CI: 53, 82) in EZH2 mutant FL patients and 34% (95% CI: 22, 48) in EZH2 wild-type FL patients.
    - The median DOR was 10.9 months (95% CI: 7.2, not estimable [NE]) in EZH2 mutant FL patients and 13.0 months (95% CI: 5.6, NE) in EZH2 wild-type patients.
- The recommended dosage of Tazverik for all indications is 800 mg orally twice daily with or without food until disease progression or unacceptable toxicity.
    - Select patients with R/R FL for treatment with Tazverik based on the presence of EZH2 mutation of codons Y646, A682, or A692 in tumor specimens. Information on FDA-approved tests for the detection of EZH2 mutation in R/R FL is available at: http://www.fda.gov/CompanionDiagnostics.