Tevimbra® (tislelizumab-jsgr) – New drug approval

- On March 14, 2024, BeiGene announced the FDA approval of Tevimbra (tislelizumab-jsgr), as a single agent, for the treatment of adult patients with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor.

- Tevimbra is a programmed death receptor-1 (PD-1) blocking antibody.

- The efficacy of Tevimbra was established in RATIONALE-302, a randomized, open-label study in 512 adult patients with unresectable advanced or metastatic ESCC who progressed on or after prior systemic chemotherapy. Patients were randomized to receive either Tevimbra or investigator's choice of chemotherapy. Patients were treated until disease progression or unacceptable toxicity. The major outcome measure was overall survival (OS). Additional outcome measures were progression-free survival (PFS), overall response rate (ORR), and duration of response (DOR).

    - Tevimbra demonstrated a statistically significant improvement in OS vs. chemotherapy. Median OS was 8.6 months for Tevimbra vs. 6.3 months for chemotherapy (hazard ratio [HR] 0.70, 95% CI: 0.57, 0.85; p = 0.0001).
    - Median PFS was 1.6 months for Tevimbra vs. 2.1 months for chemotherapy (HR 0.83, 95% CI: 0.67, 1.01).
    - The ORR was 15.2% (95% CI: 11.1, 20.2) for Tevimbra vs. 6.6% (95% CI: 3.9, 10.4) for chemotherapy.
    - Median DOR was 10.3 months (95% CI: 6.5, 13.2) for Tevimbra vs. 6.3 months (95% CI: 2.8, 8.5) for chemotherapy.

- Warnings and precautions for Tevimbra include severe and fatal immune-mediated adverse reactions; infusion-related reactions; complications of allogeneic hematopoietic stem cell transplantation; and embryo-fetal toxicity.

- The most common adverse reactions (≥ 20%), including laboratory abnormalities, with Tevimbra use were increased glucose, decreased hemoglobin, decreased lymphocytes, decreased sodium, decreased albumin, increased alkaline phosphatase, anemia, fatigue, increased aspartate aminotransferase, musculoskeletal pain, decreased weight, increased alanine aminotransferase, and cough.

- The recommended dose of Tevimbra is 200 mg administered as an intravenous infusion once every 3 weeks, until disease progression or unacceptable toxicity.

- The FDA is also reviewing Biologics License Applications (BLAs) for Tevimbra as a first-line treatment for patients with unresectable, recurrent, locally advanced, or metastatic ESCC and patients with locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma. The target action dates are July and December 2024, respectively.

- BeiGene plans to launch Tevimbra in the second half of 2024. Tevimbra will be available as a 100 mg/10 mL (10 mg/mL) solution in a single-dose vial.