Tevimbra® (tislelizumab-jsgr) – New indication

- On March 5, 2025, BeiGene announced the FDA approval of Tevimbra (tislelizumab-jsgr), in combination with platinum-containing chemotherapy, for the first-line treatment of adults with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) whose tumors express PD-L1 (≥ 1).

- Tevimbra is also approved:

    - As a single agent, for the treatment of adults with unresectable or metastatic ESCC after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor.
    - In combination with platinum and fluoropyrimidine-based chemotherapy, for the first-line treatment of adults with unresectable or metastatic HER2-negative gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1 (≥ 1).

- The approval of Tevimbra for the new indication was based on RATIONALE-306, a randomized, placebo-controlled, double-blind study in 649 patients with unresectable, recurrent, or metastatic ESCC. Patients were randomized to receive either Tevimbra or placebo in combination with investigator's choice of chemotherapy (ICC) on a 21-day cycle. The primary outcome measure was overall survival (OS).

    - Tevimbra demonstrated a statistically significant improvement in OS compared to placebo. Exploratory analysis of OS in the population with TAP < 1% population and in the CPS < 1 population showed hazard ratios (HRs) of 1.34 (95% CI 0.73, 2.46) and 1.52 (95% CI 0.81, 2.84), respectively, indicating that the improvement in the intention-to-treat (ITT) population was primarily attributed to the results observed in the subgroup of patients with PD-L1 ≥ 1.
    - In the PD-L1 TAP ≥ 1% population, median OS was 16.8 months and 9.6 months with Tevimbra and placebo, respectively (HR 0.66, 95% CI: 0.53, 0.82). In the PD-L1 CPS ≥ 1 population, median OS was also 16.8 months and 9.6 months with Tevimbra and placebo, respectively (HR 0.65, 95% CI: 0.52, 0.81).

- The most common adverse reactions (≥ 20%), including laboratory abnormalities with Tevimbra use, in combination with platinum-containing chemotherapy, were decreased neutrophil count, decreased sodium, increased glucose, anemia, fatigue, decreased appetite, increased aspartate aminotransferase, decreased potassium, increased serum creatinine, decreased calcium, increased alanine aminotransferase, diarrhea, stomatitis, and vomiting.

- The recommended dose of Tevimbra as a single agent or in combination with chemotherapy is 200 mg administered as an intravenous infusion every 3 weeks until disease progression or unacceptable toxicity.