

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Oncologic Drugs Advisory Committee (ODAC) Meeting

September 26, 2024

QUESTIONS

Morning session

1. **DISCUSSION:** In patients with HER2-negative microsatellite stable gastric/gastroesophageal junction (GEJ) adenocarcinoma, does the cumulative data support the use of PD-L1 expression as a predictive biomarker when selecting patients for treatment with PD1- inhibitors?
2. **VOTE:** Is a risk benefit assessment favorable for the use of PD-1 inhibitors in first line advanced HER2 negative microsatellite stable gastric/GEJ adenocarcinoma in patients with PD-L1 expression < 1?

Afternoon session

1. **DISCUSSION:** FDA would like the committee to discuss the risk and benefits of the treatment with anti PD-1 antibodies for the first line treatment of patients with metastatic or unresectable esophageal squamous cell carcinoma with PD-L1 expression <1.
2. **VOTE:** Is the risk: benefit assessment favorable for the use of anti-PD-1 antibodies in first line unresectable or metastatic esophageal squamous cell carcinoma with PD-L1 expression <1?