TPS3157 **Poster Session**

IDeate-PanTumor02: A phase 1b/2 study to evaluate the efficacy and safety of ifinatamab deruxtecan (I-DXd) in patients (pts) with recurrent or metastatic solid tumors.

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Background: B7-H3 is highly expressed in many solid tumors but has limited expression in normal tissues; high B7-H3 expression is associated with shorter overall survival (OS) in several tumor types. I-DXd is a B7-H3–directed antibody–drug conjugate (anti–B7-H3 mAb covalently linked to a topoisomerase I inhibitor cytotoxic payload [DXd] via an enzymatically cleavable peptide-based linker). It showed promising efficacy in pts with advanced solid tumors in the Phase 1/2 IDeate-PanTumor01 study, with objective responses in 6 of the 7 tumor types with ≥5 pts (small cell lung cancer [SCLC], esophageal squamous cell carcinoma, metastatic castration-resistant prostate cancer, squamous non-small cell lung cancer, head and neck squamous cell carcinoma [HNSCC], and endometrial cancer). I-DXd also showed encouraging antitumor activity in 88 pretreated pts with extensive-stage SCLC in the Phase 2 IDeate-Lung01 study, with greater efficacy at the 12-mg/kg than the 8-mg/kg dose (objective response rates [ORRs] of 54.8% [95% CI, 38.7–70.2] and 26.1% [95% CI, 14.3–41.1], respectively). I-DXd has demonstrated a manageable and tolerable safety profile across tumor types. We describe a study investigating the efficacy and safety of I-DXd in pts with advanced solid tumors with substantial unmet medical needs. **Methods:** IDeate-PanTumor02 (NCT06330064) is a global, multicenter, open-label, single-arm, parallel-cohort, Phase 1b/2 study in ~520 adults with recurrent or metastatic solid tumors (endometrial cancer; HNSCC; pancreatic ductal adenocarcinoma; colorectal cancer; hepatocellular carcinoma [HCC]; esophageal/gastroesophageal/gastric adenocarcinoma; urothelial carcinoma; ovarian cancer; cervical cancer; biliary tract cancer; HER2-low breast cancer [BC]; HER2-negative BC; and cutaneous melanoma). Eligible pts will have received ≥1 systemic therapy for the selected tumor type and have an ECOG PS of ≤1. The study will be divided into 2 parts: Stage 1 and Stage 2 (n≈20 per stage per cohort). Each cohort starts with Stage 1 and may continue to Stage 2 if sufficient safety and efficacy data are observed. All cohorts except the HCC cohort will receive I-DXd 12 mg/kg every 3 weeks (Q3W). The HCC cohort includes a safety run-in part to assess tolerability and the potential need for dose adjustment; the planned starting dose is 8 mg/kg Q3W, which may be escalated. Primary endpoints are ORR per investigator (all cohorts) and safety (HCC safety run-in only). Secondary endpoints are safety, duration of response, progression-free survival, OS, disease control rate, pharmacokinetics, and immunogenicity. The Kaplan–Meier method will be used to estimate time-to-event endpoints, the Brookmeyer and Crowley method for median event times, and the Clopper–Pearson exact method to summarize descriptively endpoints with proportion. Enrollment is ongoing. Clinical trial information: NCT06330064. Research Sponsor: Daiichi Sankyo, Inc., Merck, Inc.