TPS3165 Poster Session

# PROCEADE PanTumor: A phase 1b/2, multicenter study of precemtabart tocentecan (M9140), an anti-CEACAM5 antibody-drug conjugate (ADC) with exatecan payload, in patients with advanced solid tumors.

Zev A. Wainberg, Benjamin Besse, Athanasios G. Pallis, Christina Habermehl, Ken Kato; University of California, Los Angeles, Medical Center, Los Angeles, CA; Gustave Roussy Institute, Villejuif, France; Merck Santé S.A.S., an affiliate of Merck KGaA, Lyon, France; The Healthcare Business of Merck KGaA, Darmstadt, Germany; National Cancer Center Hospital, Tokyo, Japan

**Background:** CEACAM5 is a cell surface glycoprotein that is overexpressed in various carcinomas, notably in gastric cancer (GC), non-small cell lung cancer (NSCLC), pancreatic adenocarcinoma (PDAC), and colorectal cancer (CRC), but shows limited expression on healthy adult cells. Precemtabart tocentecan is an investigational anti-CEACAM5 ADC (drug-to-antibody ratio: 8) that utilizes a unique linker–payload combination to selectively deliver the topoisomerase 1 inhibitor, exatecan, to CEACAM5 overexpressing tumor cells. Preliminary clinical data from the dose-escalation part of the first-in-human study of precemtabart tocentecan in patients with metastatic CRC (PROCEADE CRC-01) demonstrated a manageable and predictable safety profile and promising preliminary efficacy in 40 heavily pretreated patients. The PROCEADE PanTumor study is a Phase 1b/2, multicenter, open-label study that aims to investigate the clinical activity of precemtabart tocentecan, either as monotherapy or in combination with other anticancer agents, in patients with advanced GC, advanced NSCLC and advanced PDAC. **Methods:** The study was designed as a matrix study with a master protocol (applicable to all substudies) and three substudy protocols (GC; NSCLC; PDAC). Based on the master protocol, patients aged ≥18 years, with an Eastern Cooperative Oncology Group performance status ≤1, adequate baseline hematological, renal, and hepatic function, ≥1 lesion that is measurable using RECIST v1.1, who have received ≥1 prior line of treatment are eligible. Patients must have an archival formalin-fixed paraffin-embedded tumor tissue or a fresh biopsy. In the respective substudies, patients with advanced or metastatic, HER2-negative GC or gastroesophageal junction adenocarcinoma; patients with advanced (Stage III; ineligible for resection/curative radiation) or metastatic NSCLC; or patients with advanced or metastatic PDAC will be included. Patient selection will be based on CEACAM5 expression level (both high and low in GC, only high in NSCLC and PDAC [$CEACAM5^{high}$: ≥50% tumor cells with immunohistochemistry [IHC] ≥2+ staining; $CEACAM5^{low}$: <50% tumor cells with IHC ≥2+ staining]), and in patients with NSCLC, *EGFR* mutation status (*EGFR*-wt and *EGFR* mut+). The primary endpoint is objective response (proportion of patients with confirmed complete/partial response [CR/PR] per RECIST v1.1, assessed by investigator). Secondary endpoints include adverse events, duration of response (RECIST v1.1), disease control (CR, PR, stable disease, or non-CR/non-progressive disease [PD] at Week 12), time to response, progression-free survival, and pharmacokinetic assessments. The study is planned to be initiated at multiple sites globally, with an estimated enrollment of 250 patients.  Clinical trial information: NCT06710132. Research Sponsor: the healthcare business of Merck KGaA, Darmstadt, Germany (CrossRef Funder ID: 10.13039/100009945).