TPS5618 **Poster Session**

TroFuse-020/GOG-3101/ENGOT-cx20: A phase 3, randomized, active-controlled, open-label, multicenter study comparing sacituzumab tirumotecan monotherapy vs treatment of physician's choice as second-line treatment for recurrent or metastatic cervical cancer.

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Background: Sacituzumab tirumotecan (sac-TMT; formerly MK-2870/SKB264) is an antibody–drug conjugate comprising a trophoblast cell-surface antigen 2 (TROP2)–antibody, a hydrolytically-cleavable linker, and the cytotoxic drug KL610023 (average drug/antibody ratio, 7.4). In an ongoing phase 1/2 study (MK-2870-001), sac-TMT monotherapy showed promising antitumor activity in participants with locally advanced unresectable/metastatic solid tumors that were refractory to standard therapies. This phase 3, randomized, open-label, multicenter study (NCT06459180) evaluates the efficacy and safety of sac-TMT monotherapy vs treatment of physician's choice (TPC) as second-line treatment in participants with recurrent/metastatic cervical cancer. **Methods:** Eligible participants are aged ≥18 years with progressive recurrent/metastatic cervical cancer, measurable per RECIST version 1.1 by the investigator, and had received 1 prior line of platinum doublet chemotherapy (±bevacizumab) and anti–PD-1/anti–PD-L1 therapy as a part of cervical cancer regimens. Participants must provide tissue from a core or excisional biopsy of a not previously irradiated tumor lesion. Approximately 666 participants will be randomly assigned 1:1 to receive either sac-TMT 4 mg/kg intravenously (IV) Q2W or TPC (pemetrexed 500 mg/m^2 IV Q3W; tisotumab vedotin 2 mg/kg IV Q3W; topotecan 1 or 1.25 mg/m^2 on days 1–5 of each 3-week treatment cycle; vinorelbine 30 mg/m^2 on days 1 and 8 of each 3-week treatment cycle; gemcitabine 1000 mg/m^2 on days 1 and 8 of each 3-week treatment cycle; or irinotecan 100 or 125 mg/m^2 on days 1, 8, 15, and 22 of each 6-week treatment cycle). Tumor imaging will be performed ≤28 days before treatment allocation/randomisation, then Q9W until week 54 and Q12W thereafter. The primary endpoint is OS; secondary endpoints include PFS assessed by blinded independent central review, objective response, duration of response, safety, time to deterioration, and patient-reported outcomes. Enrollment began in Q3 2024. Clinical trial information: NCT06459180. Research Sponsor: Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.