additional secondary endpoints included safety, progression-free survival (PFS), and overall survival (OS).

**Results:** With a data cutoff of 17 Jan 2024, 79 patients were enrolled. 97.5% had prior taxanes, 81% prior poly (ADP-ribose) polymerase inhibitors (PARPi) [74.7% of whom progressed while on PARPi], 64.6% prior bevacizumab, 98.8% had 2+ prior lines of therapy, and BRCA status was 27.8% positive, 72.2% negative. ORR was 51.9% (95% CI 40.4, 63.3), including 6 complete and 35 partial responses. The mDOR was 8.3 months (95% CI 5.5, 10.8), mPFS was 6.9 months (95% CI 5.9, 9.6); OS was not mature at data cutoff. The most common treatment-emergent adverse events (TEAEs) (all grade and grade $\geq$ 3) were blurred vision (63% and 10%), dry eye (37% and 3%), nausea (37% and 1%), keratopathy (33% and 4%), and diarrhea (30% and 3%). TEAEs led to dose delays, reductions, and discontinuations in 61%, 42%, and 16% of patients, respectively.

**Conclusions:** MIRV demonstrated clinically meaningful antitumor activity and favorable tolerability in patients with FRα-high PSOC. The efficacy and safety data support the use of MIRV in PSOC patients with $\geq$ 2 prior platinum-containing regimens or platinum allergy. Clinical Trial: NCT05041257.

**Clinical trial identification:** NCT05041257.

**Legal entity responsible for the study:** ImmunoGen, Inc.

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## 719MO A phase I/II study of rinatabart sesutecan (Rina-S) in patients with advanced ovarian or endometrial cancer

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**Background:** Rina-S is a novel folate receptor alpha (FRα)-directed ADC with sesutecan, a highly hydrophilic linker and a topoisomerase 1 inhibitor payload.

**Methods:** PRO1184-001 is an ongoing Phase 1/2 dose escalation (Part A) and expansion/optimization (Part B) study (NCT05579366) in pts with advanced cancers including ovarian (OC) and endometrial (EC). FRα expression is retrospectively tested.

**Results:** As of 02 April 2024, 53 pts were treated in Part A. Of 32 pts with OC, median number of prior therapies was 5 (1–14); 75% had received bevacizumab; 91% were platinum resistant. Of 11 pts with EC, median number of prior therapies was 3 (1–11); all had received a prior PD-1 inhibitor. Other tumor types were NSCLC, breast, and mesothelioma (n=10 total). In Part B, 35 pts with OC and 13 pts with EC were treated; the median number of prior therapies was 3 (1–4) and 3 (1–7), respectively. Rina-S doses from 60–180 mg/m$^2$ were evaluated in Part A. The MTD was 140 mg/m$^2$. Doses of 100 and 120 mg/m$^2$ were selected for evaluation in Part B. For Part A pts treated at 100 or 120 mg/m$^2$ (n=35), the most common ($\geq$20%) treatment-related adverse events (TRAEs) were nausea (n=20, 57%), neutropenia (n=18, 51%), leukopenia (n=16, 46%), anemia (n=15, 43%), thrombocytopenia (n=11, 31%), and vomiting (n=9, 26%); most events were Grade 1/2. The most common ($\geq$10%) $\geq$ Grade 3 TRAEs were neutropenia (n=12, 34%), anemia (n=9, 26%), leukopenia (n=8, 23%), and thrombocytopenia (n=5, 14%). No ocular toxicity or interstitial lung disease was observed. The emerging safety profile of Rina-S in Part B is consistent with Part A. For Part A OC and EC pts treated at 100 or 120 mg/m$^2$, the objective response rate (ORR) was 35% (8/23 pts). In Part B, ORR for OC pts randomized and treated at 100 or 120 mg/m$^2$ was 14% (2/14 pts) and 50% (6/12 pts), respectively. As of data cutoff, all confirmed responses are ongoing with a range from 6+ to 30+ wks. Antitumor activity was seen across all FRα expression levels, including FRα undetectable by IHC.

**Conclusions:** Rina-S was well tolerated at 100 and 120 mg/m$^2$, with manageable TRAEs. Promising antitumor activity was observed across a wide range of FRα expression levels. Enrollment for Part B OC pts is complete; dose optimization analysis will be presented.

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