**Results:** As of March 25, 2024, 38 pts were treated and followed up for at least 17 weeks or 2 tumor assessments (3 received sac-TMT 3 mg/kg, 35 received sac-TMT 5 mg/kg). The median follow-up was 6.2 mo. The median age was 52 years. 76.3% had squamous histology. 47.4% had received two prior lines of therapy, 52.6% had received bevacizumab, and 42.1% had received anti-PD-1 based therapy. The ORR was 57.9% (22/38, 3 unconfirmed), with 3 complete responses. Median DoR was not reached and 6-mo DoR rate was 82.1%. Responses were also observed in pts were pre-treated with anti-PD-1 based therapy (ORR 68.8%, 11/16). Median PFS was not reached and 6-mo PFS rate was 65.7%. Grade $\geq$ 3 treatment-related AEs (TRAEs) occurred in 47.4% of pts. The most common Grade $\geq$ 3 TRAEs were neutrophil count decreased (23.7%), anemia (21.1%) and WBC decreased (15.8%). TRAEs led to dose reduction of sac-TMT in 44.7% of pts. TRAE led to discontinuation of sac-TMT in 1 pt (2.6%). No TRAEs led to discontinuation of both drugs.

**Conclusions:** Sac-TMT plus pembrolizumab demonstrated promising and durable antitumor activity with manageable safety profile. No new safety signal was observed. Considering the activity of this combination among pts who were pre-treated with anti-PD-1 based therapy, further investigation is warranted.

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**Legal entity responsible for the study:** Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd., Chengdu, China.

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## 717MO SHR-A1921 in platinum-resistant ovarian cancer (PROC): data from a first-in-human (FIH) phase I study

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**Background:** SHR-A1921 is an ADC composed of a humanized anti-TROP-2 IgG1 mAb attached to a DNA topoisomerase I inhibitor via a tetrapeptide-based cleavable linker. The FIH study of SHR-A1921 showed manageable safety and encouraging anti-tumor activity in patients (pts) with advanced solid tumors. Here, we present the results in PROC pts.

**Methods:** Pts with PROC (defined as platinum-free interval [PFI] <6 mo) were enrolled, regardless of TROP-2 expression status. Two tolerable dose levels, 3.0 mg/kg (D1, Q3W) and 2.0+2.0 mg/kg (D1 and D8, Q3W), were selected for dose optimization.

**Results:** As of Mar 20, 2024, 46 PROC pts were enrolled (3.0 mg/kg, n=26; 2.0+2.0 mg/kg, n=20). 39.1% of pts were identified with primary platinum resistance (defined as PFI <6 mo after first-line platinum-based chemo); 34.8% of pts had a PFI of <4 wk following the most recent platinum-based chemo.78.3% had received $\geq$2 lines of platinum-based chemo; 45.7% had received $\geq$1 line of non-platinum chemo after confirmed platinum resistance. Most pts had received prior bevacizumab (69.6%) and PARP inhibitors (58.7%). Median follow-up was 7.4 mo (range 0.9-22.7). Among the evaluable pts, ORR was 48.8% (21/43; 95% CI 33.3-64.5) and DCR was 97.7% (42/43; 95% CI 87.7-99.9). Median DoR was 6.4 mo (95% CI 4.7-not reached). 47.6% (10/21) of confirmed responses were still ongoing. Median PFS was 7.2 mo (95% CI 4.4-11.1). Median OS was not reached, and 6-mo OS rate was 91.9% (95% CI 76.9-97.3). SHR-A1921 was effective at both 3.0 mg/kg and 2.0+2.0 mg/kg (table). Grade $\geq$3 TRAEs occurred in 23 of the 46 pts (50.0%), with the most common ($\geq$5%) being stomatitis (28.3%; 11.5% in 3.0 mg/kg and 50.0% in 2.0+2.0 mg/kg cohort), anemia (8.7%) and decreased neutrophil count (6.5%). No interstitial lung disease or TRAEs leading to death occurred.

**Table: 717MO Efficacy summary**

| | 3.0 mg/kg (N=26) | 2.0+2.0 mg/kg (N=20) | All (N=46) |
|---|---|---|---|
| Evaluable pts, n | 26 | 17 | 43 |
| BOR, n (%) | | | |
| CR | 1 (3.8) | 0 | 1 (2.1) |
| PR | 10 (38.5) | 10 (58.8) | 20 (41.7) |
| SD | 15 (57.7) | 6 (35.3) | 21 (47.9) |
| PD | 0 | 1 (5.9) | 1 (2.1) |
| ORR, % (95% CI) | 42.3 (23.4-63.1) | 58.8 (32.9-81.6) | 48.8 (33.3-64.5) |
| DCR, % (95% CI) | 100.0 (86.8-100.0) | 94.1 (71.3-99.9) | 97.7 (87.7-99.9) |
| DoR (mo), median (95% CI) | 9.9 (4.5-NR) | 6.3 (3.0-NR) | 6.4 (4.7-NR) |
| PFS (mo), median (95% CI) | 7.9 (4.2-NR) | 6.9 (4.2-9.6) | 7.2 (4.4-11.1) |
| 6-mo OS rate, % (95% CI) | 95.0 (69.5-99.3) | 88.1 (60.2-96.9) | 91.9 (76.9-97.3) |

BOR, ORR, DCR and DoR were analyzed in treated pts evaluable for anti-tumor response. PFS and 6-mo OS rate were analyzed in all treated pts. NR, not reached.

**Conclusions:** SHR-A1921 demonstrated promising efficacy with a manageable safety profile in heavily pretreated pts with PROC. A pivotal phase 3 study is currently in preparation.

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**Legal entity responsible for the study:** Jiangsu Hengrui Pharmaceuticals Co., Ltd.

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## 718MO Mirvetuximab soravtansine (MIRV) in recurrent platinum-sensitive ovarian cancer (PSOC) with high folate receptor-alpha (FRα) expression: Results from the PICCOLO trial

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**Background:** MIRV is an antibody-drug conjugate comprising an FRα-binding antibody, cleavable linker, and maytansinoid DM4 payload, a potent tubulin-targeting agent and is FDA approved in patients with platinum-resistant ovarian cancer who received 1-3 prior treatment regimens. PICCOLO is a single-arm Phase 2 study evaluating the efficacy and safety of MIRV in patients with PSOC, primary peritoneal, or fallopian tube cancer.

**Methods:** PICCOLO enrolled PSOC patients with high ($\geq$ 75% of cells with PS2+ staining intensity) FRα expression by immunohistochemistry (VENTANA FOLR1 [FOLR1-2.1] RxDx Assay) with at least 2 prior lines of platinum-containing therapy or documented platinum allergy. Patients received MIRV at 6 mg/kg, adjusted ideal body weight, on Day 1 of a 21-day cycle until disease progression or unacceptable toxicity. The primary endpoint was confirmed objective response rate (ORR) per RECIST v1.1 by the investigator; key secondary endpoint was duration of response (DOR);

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.

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**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.

**Clinical trial identification:** NCT05579366.

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