to an overall poor prognosis. There have been conflicting results regarding the benefit of immunotherapy using anti-PD-1/PD-L1 blockade and minimal data on the activity of combined anti-PD-1/CTLA-4 blockade. The MoST-CIRCUIT trial evaluated nivolumab (nivo) and ipilimumab (ipi) combination treatment in this patient population.

Methods: Pts with advanced OCCC/UCCC were enrolled across 14 Australian sites. Pts received nivo 3mg/kg and ipi 1mg/kg q3 weekly for 4 doses, followed by nivo 480mg q4 weekly for 96 weeks, until disease progression or the development of unacceptable toxicity. Response (RECIST 1.1) was assessed every 12 weeks. Co-primary endpoints were objective response rate (ORR) and 6 month-progression free-survival (PFS). Tumour genomic profiling has been performed by NGS using the TSO500 assay.

Results: 28 pts (24 OCCC and 4 UCCC) were enrolled with 75% being pre-treated with one line of therapy. ORR was 50% in the overall population (13%CR, 37%PR) and 50% in the OCCC and UCCC subgroups respectively, median duration of response has not been reached, with all responses ongoing at 6 months. The 6-month-PFS was 52% with the median OS being 9.9 months. The median TMB for the population was 2.4/MB (range 1-13.9) and although being overall low, correlated with response (3.1/MB versus 1.15/MB, Mann-Whitney p=0.03). Tumour mutational analysis (N=18) revealed frequent mutations in ARID1A (44%), PIK3CA (39%), SPOP (22%), TERT promoter (22%), KRAS (17%) with responses being predominately seen in ARID1A WT tumours. 7 pts (25%) experienced a grade 3/4 immune−related adverse event and grade 5 myocarditis occurred in one patient.

Conclusions: Immunotherapy using combined anti-CTLA-4/PD-1 blockade demonstrated encouraging activity with a high rate of durable responses in pts with advanced gynaecological CCC. This regimen should be further investigated in this patient population of unmet medical need. Tumour genomic analysis and TMB may be helpful in predicting response.

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Legal entity responsible for the study: Olivia Newton-John Cancer Research Institute.

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714MO Datopotamab deruxtecan (Dato-DXd) in patients with endometrial (EC) or ovarian cancer (OC): Results from the phase II TROPION-PanTumor03 study

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Background: The Phase 2, multicentre, open-label TROPION-PanTumor03 study (NCT05489211) comprises independent cohorts evaluating the TROP2-directed antibody-drug conjugate Dato-DXd as monotherapy and in combination in several tumour types. We present results from patients (pts) who received Dato-DXd monotherapy in the EC and OC cohorts.

Methods: The EC cohort enrolled pts with histologically documented recurrent unresectable advanced/metastatic endometrial carcinoma, whose disease had progressed on ≥1 line of platinum-based chemotherapy (CT). The OC cohort enrolled pts with histologically documented recurrent unresectable advanced/metastatic high-grade ovarian, fallopian tube, or primary peritoneal carcinoma whose disease had progressed after ≥1 line of platinum-based CT. Patients with platinum-sensitive and platinum-resistant OC were included. Both cohorts had ECOG PS of 0 or 1 and were unselected for TROP2 expression. The Dato-DXd monotherapy regimen is 6 mg/kg IV Q3W for both cohorts. Primary endpoints are objective response rate (ORR) and safety/tolerability.

Results: At data cut-off (March 1, 2024), 40 pts with EC and 35 pts with OC had received Dato-DXd. In the EC cohort, (median of 1 prior line of therapy; range 1−2) confirmed ORR was 27.5% (1 complete response [CR], 10 partial responses [PR]) and disease control rate (DCR) was 85.0%. Duration of response (DoR) was not yet reached. Median progression-free survival (PFS) was 6.3 months (95% CI 2.8−not yet reached). In the OC cohort (median of 2 prior lines of therapy; range 1−4), confirmed ORR was 42.9% (1 CR, 14 PR). DCR was 91.4%, DoR was 5.6 months and median PFS was 5.8 months (95% CI 4.1−7.1). Efficacy by subgroups will be presented. Safety is summarised in the table.

Table: 714MO

Incidence of adverse events (AEs), n (%)	Endometrial cohort N=40	Ovarian cohort N=35
Treatment-related AEs (TRAEs)	37 (92.5)	35 (100.0)
Grade ≥3 TRAEs	17 (42.5)	16 (45.7)
Any TRAE leading to: Dose reduction Dose interruption Discontinuation Death	10 (25.0) 11 (27.5) 2 (5.0) 0	11 (31.4) 11 (31.4) 2 (5.7) 0
Most common TRAEs:		
Stomatitis, all grades	21 (52.5)	22 (62.9)
Grade ≥3	1 (2.5)	3 (8.6)
Nausea, all grades	15 (37.5)	17 (48.6)
Grade ≥3	2 (5.0)	1 (2.9)
Alopecia, all grades	10 (25.0)	17 (48.6)
Adjudicated drug-related interstitial lung disease, n	1 (Grade 3)	1 (Grade 3)

Conclusions: Dato-DXd monotherapy demonstrated encouraging efficacy and a manageable safety profile in pts with recurrent endometrial or ovarian cancer.

Clinical trial identification: NCT05489211. Release date: 5 August 2022.

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715MO Safety and efficacy of sacituzumab tirumotecan (sac-TMT) in patients (pts) with previously treated advanced endometrial carcinoma (EC) and ovarian cancer (OC) from a phase II study

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Background: Trophoblast cell surface antigen 2 (TROP2) is highly expressed in EC and OC. Sac-TMT (also known as MK-2870/SKB264) is a TROP2 ADC developed with a hydrolytically cleavable linker to conjugate a belotecan-derivative topoisomerase I inhibitor. Here, we report the preliminary results from a Phase 2 study in pts with advanced EC and OC (KL264-01, NCT04152499).

Methods: Advanced EC and OC pts who have been previously treated with platinum-based chemo were given sac-TMT at 5 mg/kg Q2W until disease progression, unacceptable toxicity or withdrawal of consent. Tumor assessment was performed every 8 weeks per RECIST v1.1 by investigator. The TROP2 expression was scored using the semi-quantitative H-score method, and cut-off point was set to 200.

Results: As of March 5, 2024, 44 EC pts were enrolled and median follow-up time was 7.2 mo. 52.3% of pts had received $\geq$ 2 prior lines of therapy. The ORR was 34.1% (15/44, 12 confirmed) and DCR was 75%. Median PFS was 5.7 mo (95% CI: 3.7, 9.4) with 6-mo PFS rate of 47.5%. In the pts with TROP2 IHC H-score $>$ 200 (n=12) or H-score $\leq$ 200 (n=28), the ORR was 41.7% (5/12, 3 confirmed) and 35.7% (10/28, 9 confirmed) respectively. 40 OC pts were enrolled and median follow-up time was 28.2 mo. All pts had received $\geq$ 2 prior lines of therapy (80% of pts $\geq$ 3 prior lines). 87.5% of pts were platinum-resistant. The ORR was 40% (16/40, 14 confirmed) and DCR was 75%. mPFS was 6.0 mo (95% CI: 3.9, 7.3); mOS was 16.5 mo (95% CI: 10.7, NE). In the pts with TROP2 IHC H-score $>$ 200 (n=13) or H-score $\leq$ 200 (n=22), the ORR was 61.5% (8/13, 7 confirmed) and 27.3% (6/22, 6 confirmed) respectively. In the pts with platinum-resistant (n=35), mPFS was 6.0 mo (95% CI: 5.3, 7.3) and mOS was 16.1 mo (95% CI: 10.5, NE). Safety of the EC and OC pts is presented in the table.

Table: 715MO Safety summary

	EC (N = 44)	OC (N = 40)
Category		
TRAEs	44 (100%)	40 (100%)
$\geq$ Grade 3 TRAEs	32 (72.7%)	27 (67.5%)
serious TRAEs	9 (20.5%)	15 (37.5%)
TRAEs leading to discontinuation	1 (2.3%)	5 (12.5%)
$\geq$15% $\geq$ Grade 3 TRAEs		
Neutrophil count decreased	19 (43.2%)	12 (30.0%)
White blood cell count decreased	18 (40.9%)	9 (22.5%)
Anaemia	13 (29.5%)	14 (35.0%)
Stomatitis	6 (13.6%)	6 (15.0%)

Conclusions: Sac-TMT monotherapy has shown promising anti-tumor activity with a manageable safety profile in pts with heavily pre-treated advanced EC and OC.

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716MO Efficacy and safety of sacituzumab tirumotecan (sac-TMT) plus pembrolizumab in patients with recurrent or metastatic cervical cancer

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Background: Anti-PD-1 antibody is the standard therapy for recurrent or metastatic (R/M) cervical cancer (CC) patients (pts) after platinum-based chemotherapy. It was shown that ADC combined with PD-1/L1 antibody has a potential additive effect. Sac-TMT (also known as MK-2870/ SKB264) is a TROP2 ADC developed with novel linker to conjugate a belotecan-derivative topoisomerase I inhibitor. Here, we report the efficacy and safety results from the CC cohort in an ongoing Phase 2 basket study (SKB264-II-06, NCT05642780).

Methods: Pts with R/M CC who had progressed on or after platinum-doublet chemotherapy and received no more than 2 systemic therapies for R/M disease were enrolled. Sac-TMT 3 or 5 mg/kg Q2W+ pembrolizumab 400 mg Q6W were assessed in safety run-in period and the doses deemed well tolerated were being explored in expansion period. Tumor assessments per RECIST 1.1 were performed once every 8 weeks for the first 12 mo, and every 12 weeks thereafter.