

14.85% (95% CI 14.01-15.68) respectively. Pooled median PFS was 7.17 months and 3.30 months respectively. In multiple linear regression model administration of platinum chemotherapy was the strongest predictor of RR [B value 0.503 ($p < 0.001$)]. Cisplatin (RR 39.9%; 95% CI 35.8-44.0%) and carboplatin (RR 42.3%; 95% CI 37.0-47.6%) were associated with better RR compared to oxaliplatin (RR 28.1%; 95% CI 23.9-32.3).

Conclusions: This systematic review shows that patients with 'platinum-resistant' ovarian carcinoma may derive significant benefit from reintroduction of platinum agents and their value should be evaluated in further randomized trials.

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832P GEICO1601-ROLANDO trial: A multicentric single arm phase II clinical trial to evaluate the combination of olaparib and pegylated liposomal doxorubicin for platinum-resistant ovarian cancer

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Background: The benefit of olaparib (OLA) in platinum-resistant ovarian cancer (PROC) patients (pts) with BRCA wild-type tumors is scarce. The combination with DNA-damaging chemotherapy may be synergistic and improve the activity of OLA.

Methods: Patients with high-grade serous or endometrioid and one previous PROC (between 28 days-6 months after last platinum) were eligible regardless of BRCA status. Pts had received ≤ 4 previous lines (up to 5 in BRCA-mut pts), and primary PROC was only allowed in the presence of BRCA-mut otherwise at least one previous platinum-sensitive relapse was required. Pts received 6 cycles of OLA 300 mg b.i.d + pegylated liposomal doxorubicin (PLD) 40 mg/m² (PLD40) intravenously q28d followed by OLA 300 mg b.i.d. until progression or toxicity. Due to high toxicity a protocol amendment was performed to reduce PLD to 30 mg/m² (PLD30). The primary endpoint was progression-free survival at 6 months (6mPFS) by RECIST 1.1 and the threshold for futility was 40% 6mPFS.

Results: 31 pts (ITT cohort) received at least 1 cycle, but only 20 pts were in the per protocol cohort (PP). ITT median age was 58.03 years, ECOG 0/1: 32.3/67.7%, serous subtype 84%. PP median age was 60 y.o., ECOG 0/1: 25%/75%, serous subtype: 85% and BRCA status was WT/mut/unk: 75%/20%/5%. Median of prior lines was 2 (1-4). Median number of cycles was 4.2 (0.9-19.5) for OLA and 4 (2-6) for PLD. After a median follow-up of 9.29 (0.9-21.3) mo, the 6mPFS in the ITT population was 44.2% (95%CI 28.7-68.1%) and median PFS 5.32 mo. In the PP cohort 6mPFS was 46.1% (95% CI 27.2-78.3) with a median PFS of 5.42 mo (4-12). 65% pts achieved stable disease and 25% partial response (overall control rate 90%). 74% of ITT pts had a Grade ≥ 3 adverse event (AE), being the most frequent neutropenia/anemia/febrile neutropenia: 39%/19%/10%. SAEs were less frequent in PLD30 (N=14) than in PLD40 (n=17): 21%/47%, as well as PLD delays 30/40: 30%/45% and reductions 30/40: 10%/25%.

Conclusions: OLA+PLD combination has shown clear activity with 46% 6mPFS rate in PROC regardless of BRCA status. PLD at 30 mg/m² was better tolerated in the combination.

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833P Mirvetuximab soravtansine (MIRV), a folate receptor alpha (FR α)-targeting antibody-drug conjugate (ADC), in combination with carboplatin (CARBO) and bevacizumab (BEV): Final results from a study in patients (pts) with recurrent platinum sensitive ovarian cancer

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Background: MIRV is an ADC comprising a FR α -binding antibody, cleavable linker, and the maytansinoid DM4, a potent tubulin-targeting agent. MIRV is being evaluated with carboplatin and BEV in recurrent platinum-sensitive (RPS) ovarian cancer.

Methods: Pts had RPS ovarian cancer (last platinum-free interval (PFI) >6 mo), 1 or 2 prior lines of therapy, and FR α -positivity by IHC (medium/high expression; $\geq 50\%$ $\geq 75\%$ of cells with PS2+ staining intensity). MIRV was given at 6 mg/kg (adjusted ideal body weight) with CARBO (AUC 5) and BEV (15 mg/kg) IV on Day 1 of a 21-day cycle. MIRV and BEV were continued as maintenance after completing CARBO. Responses were assessed with RECIST 1.1.

Results: 41 pts received full dosing, median age of 63 years; 73% had 1 prior line of therapy; 42% had prior PARPi; 24% had prior BEV; 54% had a PFI of 6 to ≤ 12 mos; 9 pts remain on study, with a 17 mo median duration of follow-up. The most common treatment-related AEs were consistent with the safety profile of MIRV, albeit more frequent: diarrhea (all grades, 83%; [gr 3, 10%]), nausea (76%; [2%]), fatigue (76%; [5%]), and vision blurred (68%; [0%]). AEs seen with CARBO, thrombocytopenia [51% ≥ 3], neutropenia [39% ≥ 3], and infusion related reactions (12%; [gr 4 2%]), and BEV, hypertension (gr 3,10%), were also observed. Grade 2 peripheral neuropathy was seen in 22% (no ≥ 3 events), and alopecia in 2%. The confirmed ORR was 81% (95% CI, 65, 91), with a median duration of response (DOR) of 10.7 mos (95% CI, 8,14) and median progression free survival (PFS) of 12.0 mos (95% CI, 9, 15) for all pts. In pts with 1 prior, the ORR was 90%, (95% CI, 74, 98), DOR of 9.7 mos (95% CI, 8,14) and PFS of 11.9 mos (95% CI 9, 15).

Conclusions: MIRV was readily combined with standard dosing of BEV and CARBO, with a manageable AE profile as anticipated for this triplet. The clinical activity is encouraging, similar to outcomes with current standard of care. These results support further exploration of this novel combination as an alternative to current treatment regimens for recurrent platinum sensitive disease.

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Legal entity responsible for the study: ImmunoGen.

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834P A phase II study of gemcitabine, cisplatin, and bevacizumab for first recurrent and refractory ovarian clear-cell carcinoma (KCOG-G1601 trial)

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Background: Patients with advanced ovarian clear-cell carcinoma (OCC) have poor prognosis in the absence of an effective standard treatment. The response rate of chemotherapy for relapsed OCC is <10%. Gemcitabine and cisplatin are reported to have a synergic effect on ovarian cancer. Evidence indicates that addition of bevacizumab to a chemotherapy regimen improves progression-free survival. We conducted a multi institutional phase II trial in Japan to examine the efficacy and safety of a gemcitabine, cisplatin, and bevacizumab combination (GPB) therapy for OCC.

Methods: Eighteen first recurrence or refractory patients with pathologically confirmed OCC and having evaluable region judged by RECIST were recruited between January 2017 and May 2019. Gemcitabine (1,000 mg/m²), cisplatin (40 mg/m²), and bevacizumab (10 mg/kg) were administered intravenously on day 1 and 15 every 28 days for 6–10 cycles until the progression of disease or appearance of intolerable toxicity. The primary endpoint was the overall response rate. The secondary endpoints included disease control rate and adverse events, among others. The trial was approved by institutional ethics boards of the participating institutions, and registered in UMIN (ID 000023097).

Results: Fifteen patients (83.3%) completed 6–10 treatment cycles, except for three patients (two with adverse events and one with PD). Overall response rate was 61.1% (CR 3, PR 8) and disease control rate was 88.9% (CR 3, PR 8, SD 5). Median duration of response was 10.5+ months (range: 4.7–34.1+). Hematological adverse events (AEs) of any grade were observed in 88.9% patients; those of grade 3 and 4 were observed in 16.7% and 5.6% (one patient with neutropenia) patients. Non-hematological AEs of any grade were observed in all patients; those of grade 3 and 4 were observed in 27.8% and 5.6% (one patient with serous retinal detachment) patients.

Conclusions: GPB therapy showed a very high response rate and acceptable toxicity and is promising for OCC.

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835P Clinical outcomes of advanced/ recurrent ovarian clear cell carcinoma in a multi-ethnic Asian cohort following bevacizumab and immune checkpoint inhibitor therapy

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Background: Ovarian clear cell carcinoma (OCCC) is associated with chemotherapy resistance. Limited data are available regarding the efficacy of targeted therapies such as anti-PD1/PDL1 checkpoint inhibitors (CPI) and bevacizumab (Bev) in OCCC. We characterized the molecular features and treatment outcomes of OCCC patients (pts) treated at our institution.

Methods: Retrospective review of medical records and next-generation sequencing (NGS) data, was performed on 157 OCCC pts treated between 2000-2020. Treatment response was assessed by RECIST1.1.

Results: Median age was 54 yrs (range 26-82). 70% pts were Chinese, 12.1% Malay and 7% Indian. At the time of diagnosis, 84(53.5%) had stage I, 17(10.8%) stage II, 42(26.8%) stage III and 13(8.3%) stage IV disease. 127/157(80.9%) pts had optimal debulking. Of 101 stage I-II pts, no difference in relapse-free survival was noted by stage, age, race or chemotherapy on multi-variate analysis. 89/157 pts had advanced/relapsed disease (advOCCC), 22/89(24.7%) pts received Bev, 21/89(23.6%) received CPI and 19/89(21.3%) underwent secondary debulking. An improvement in median progression-free survival (PFS) was noted for advOCCC pts receiving chemotherapy (CTX) + Bev compared to CTX alone in the first-line (17.2 vs 10.5mth, p>0.05), and second-line settings (5.1 vs 3.6mth, p>0.05), respectively. Of 21 pts who received CPI, 17 were evaluable. ORR was 17.6% (3/17) with 3 PR, 3 SD and 11 PD as best response. 2 pts had durable response to pembrolizumab, receiving 29 and 36 cycles of pembrolizumab respectively. 1 durable responder was re-challenged with pembrolizumab plus Bev after PD on pembrolizumab monotherapy, and responded for additional 8mth. NGS on 21 advOCCC tumors revealed common (>20%) mutations in *PI3KCA*(61.9%), *ARID1A*(57.1%), *TP53*(38.1%), *KRAS*(28.6%) and *ERBB3* amplification (23.8%). No mutation in mismatch-repair genes was detected. Median tumor mutational burden was 4 (range 0-11). Mutations in the *PI3K/AKT/PTEN/MTOR* pathway were associated with worse first-line PFS (Cox regression 1.26, p=0.05).

Conclusions: Encouraging and durable responses were observed following the use of Bev and CPI in advOCCC. Further trials are warranted.

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836P Safety and efficacy of XMT-1536 in ovarian cancer: A subgroup analysis from the phase I expansion study of XMT-1536, a NaPi2b antibody-drug conjugate

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Background: XMT-1536 is a first-in-class ADC targeting NaPi2b, the sodium-dependent phosphate transport protein, broadly expressed in solid tumors such as serous epithelial ovarian cancer. XMT-1536 is being evaluated in patients (pts) with ovarian cancer and non-small cell lung adenocarcinoma in a phase I study (NCT03319628) and has shown a favorable safety profile and evidence of clinical activity. Here, we report on the safety and efficacy of XMT-1536 in pts with platinum-resistant ovarian cancer in the expansion portion of the phase I study.

Methods: The expansion study is enrolling pts with platinum-resistant high grade serous ovarian, fallopian tube, or primary peritoneal cancer with up to 3 prior lines of therapy and pts with 4 prior lines of therapy regardless of platinum status. Doses of 36 and 43 mg/m² administered intravenously every 4 weeks (q4w) are being evaluated. Tumor tissue will be retrospectively evaluated for NaPi2b expression.

Results: As of 01-May-2020, 27 pts with ovarian cancer have enrolled: median age was 70 years (range 55 to 85); median prior lines of therapy was 3 (range 1 to 5); >50% had received prior bevacizumab and/or a PARP inhibitor. Twelve pts were dosed at 36 mg/m² and 15 pts were dosed at 43 mg/m², the MTD determined in dose escalation. The most frequently (≥20%) reported treatment-related adverse events were fatigue, nausea, vomiting, pyrexia, decreased appetite, diarrhea, and transient increase in AST. As of 01-May-2020, 20 pts were evaluable for response assessment. Treatment with XMT-1536 yielded 2 complete and 5 partial responses with an objective response rate of 35% and disease control rate of 80%, with a favorable trend toward response in tumors with higher NaPi2b expression. Data on safety, response, duration of response, and correlation of response with NaPi2b expression will be presented. At the time of presentation