PharmaMar, Precision Therapeutics, Regeneron, Roche, Sanofi, Seagen, Sumitomo Dainippon Pharma Oncology, Inc., Sutro Biopharma, Tesaro, Tracon Pharma, Verastem. D. 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LBA32 A randomized, phase II, dose optimization of gotistobart, a pH-sensitive anti-CTLA-4, in combination with standard dose pembrolizumab in platinum-resistant recurrent ovarian cancer: Safety, efficacy and dose optimization (PRESERVE-004/GOG-3081)

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Background: Gotistobart (ONC-392/BNT316) is a humanized anti-CTLA-4 mAb that preserves CTLA-4 immune checkpoint activity by avoiding lysosomal degradation. The safety and clinical activity of gotistobart monotherapy in ovarian cancer was previously reported [https://doi.org/10.1136/jitc-2022-SITC2022.0564]. We report safety and efficacy results of gotistobart + pembrolizumab in a randomized, open-label, multicenter phase 2 trial in patients with PROC.

Methods: Patients with platinum-resistant high-grade serous OC, tubal or peritoneal cancer who previously received 1 line of platinum-based therapy and progressed between 3-6 months, or received ≥1 line and progressed within 6 months of last dose, were randomized 1:1 to receive different doses of gotistobart + pembrolizumab 200 mg, Q3W. Primary endpoints are ORR (RECIST 1.1) and safety. Secondary endpoints include PFS and OS.

Results: As of May 24, 2024, 83 patients had received ≥1 dose of gotistobart + pembrolizumab with 33 and 29 patients in 1 mg/kg and 2 mg/kg gotistobart + pembrolizumab groups, respectively. At the safety and efficacy cutoff date of May 10, 2024, with a median follow-up of 2.1 months (range 0.1-9.2), grade ≥3 treatment-related adverse events (TRAEs) were observed in 35.7% and 31.0% patients in 1 mg/kg or 2 mg/kg groups, respectively. No grade 5 TRAEs were observed. Common grade 3 TRAEs from combined groups were increased ALT and AST (both 7.0%), and diarrhea (5.3%). Unconfirmed ORR was 31.8% (7/22; 95% CI 13.9-54.9) and 36.4% (8/22; 95% CI 17.2-59.3) in 1 mg/kg and 2 mg/kg groups, respectively.

Table: LBA32

Gotistobart + 200 mg Pembrolizumab Q3W Cutoff date: 10 May 2024	1 mg/kg n=28	2 mg/kg n=29
Safety		
Treatment cycles, Mean (Range)	3.6 (1-9)	3.4 (1-9)
Treatment duration in months, Mean (Range)	2.71 (0.1-7.6)	2.55 (0.3-7.1)
Any TEAEs, N (%)	25 (89.3)	26 (89.7)
TRAEs: All grades, N (%)	21 (75.0)	20 (69.0)
TRAEs: Grade ≥ 3, N (%)	10 (35.7)	9 (31.0)
irAE All grades, N (%)	11 (39.3)	13 (44.8)
irAE: Grade ≥ 3, N (%)	5 (17.9)	8 (27.6)
TRAE leading to study drug discontinuation	4 (14.3)	3 (10.3)
Efficacy		
Efficacy-evaluable population	22	22
Unconfirmed ORR, N (%)	7 (31.8)	8 (36.4)
CR	1 (4.5)	1 (4.5)
PR	6 (27.3)	7 (31.8)
SD	6 (27.3)	2 (9.0)
PD*	9 (40.9)	12 (54.5)

*PD included those without post baseline disease assessment

Conclusions: Early results show encouraging safety and clinical activity in PROC patients receiving gotistobart + pembrolizumab.

Clinical trial identification: NCT05446298.

Legal entity responsible for the study: OncoC4 Inc, BioNTech SE.

Funding: OncoC4 Inc, BioNTech SE.

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LBA33 ICON9: International phase III randomized study to evaluate the efficacy of maintenance therapy with olaparib and cediranib or olaparib alone in patients with relapsed platinum-sensitive ovarian cancer following a response to platinum-based chemotherapy

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Background: Although many patients with recurrent ovarian cancer respond to platinum-based therapy, the duration of benefit is often short. Maintenance therapy with olaparib, a poly-ADP ribose polymerase inhibitor (PARPi), or cediranib, a vascular endothelial growth factor receptor inhibitor, prolongs progression-free survival (PFS). ICON9 investigated these agents in combination.

Methods: ICON9, an international academic phase III trial, randomised (1:1) patients with high grade platinum-sensitive recurrent ovarian cancer responding to chemotherapy to receive maintenance oral olaparib 300mg twice daily alone (*O*) or with cediranib 20mg once daily (*O+C*). Stratification was by country, tumour BRCA (tBRCA), prior bevacizumab, platinum-free interval, surgery at relapse. No prior PARPi was allowed. The primary endpoint was PFS.

Results: 337 patients were randomised from 48 centres in 4 countries (Aug2018–Feb2023). Arms were well balanced, median age was 63 years (range:34–85) and 77.2% tBRCA wild-type (wt). At 37.0 months (mo) median follow-up, median PFS was 13.9 vs 11.0 mo (HR=0.84, 95%CI:0.65–1.07, p=0.24) and median OS 37.2 vs 37.8 mo (HR=0.92, 95%CI:0.67–1.25, p=0.81) in *O+C* and *O* respectively. Restricted median survival times (RMST) show that in the first 24 mo *O+C* had on average 1.9 mo (95%CI:0.2–3.6) more time progression-free than *O* (14.7 vs 12.8 mo). In the tBRCAwt group (n=260), PFS HR=0.77 (95%CI:0.58–1.01) and OS HR=0.95 (95%CI:0.67–1.35). There were more grade ≥3 adverse events with *O+C* (60.7% vs 36.6%); median 11 (range:0-55) and 8 (0-51) cycles of *O+C* or *O* received.

Table: LBA33

Endpoint	Olaparib + Cediranib	Olaparib alone
Progression-Free Survival, months		
Median (95% CI)	13.9 (95% CI: 11.3–16.1)	11.0 (95% CI: 8.4–12.8)
12-month RMST (95% CI)	9.9 (95% CI: 9.4–10.4)	8.7 (95% CI: 8.2–9.3)
24-month RMST (95% CI)	14.7 (95% CI: 13.5–15.9)	12.8 (95% CI: 11.5–14.1)
Hazard Ratio (95% CI), p-value	0.84 (95% CI: 0.65–1.07), p=0.24	
Overall Survival, months		
Median (95% CI)	37.2 (95% CI: 29.3–44.5)	37.8 (95% CI: 26.9–45.0)
12-month RMST (95% CI)	11.8 (95% CI: 11.7–11.9)	11.7 (95% CI: 11.5–11.9)
24-month RMST (95% CI)	21.7 (95% CI: 21.0–22.4)	21.5 (95% CI: 20.8–22.3)
Hazard Ratio (95% CI), p-value	0.92 (95% CI: 0.67–1.26), p=0.81	

Conclusions: Maintenance *O+C* did not improve efficacy compared to *O*. PARPi alone led to better than anticipated outcomes. Translational work to identify patients who might benefit most from this approach is ongoing.

Clinical trial identification: EudraCT: 2017-000161-75.

Legal entity responsible for the study: University College London.

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