

Abstract P0007LBA/#1550 Table 2

			Responders/Total	ORR by INV, % (95% CI)
Endometrial	HER2 amp	ISH+	11/13	84.6 (54.6, 98.1)
		ISH-	9/20	45.0 (23.1, 68.5)
		Unknown	3/7	42.9 (9.9, 81.6)
	Plasma HER2amp*	ERBB2 amplified	10/11	90.9 (58.7, 99.8)
		Not detected	13/29	44.8 (26.4, 64.3)
		Unknown <sup>†</sup>	0	0
Cervical	HER2 amp	ISH+	6/10	60.0 (26.2, 87.8)
		ISH-	12/26	46.2 (26.6, 66.6)
		Unknown	2/4	50.0 (6.8, 93.2)
	Plasma HER2amp*	ERBB2 amplified	3/4	75.0 (19.4, 99.4)
		Not detected	16/35	45.7 (28.8, 63.4)
		Unknown <sup>†</sup>	1/1	100.0 (2.5, NE)
Ovarian	HER2 amp	ISH+	6/10	60.0 (26.2, 87.8)
		ISH-	9/25	36.0 (18.0, 57.5)
		Unknown	3/5	60.0 (14.7, 94.7)
	Plasma HER2amp*	ERBB2 amplified	1/1	100.0 (2.5, NE)
		Not detected	15/37	40.5 (24.8, 57.9)
		Unknown <sup>†</sup>	2/2	100.0 (15.8, NE)

HER2 amplification was evaluated centrally using Ventana dual ISH on archival tissue and detected in baseline plasma ctDNA using Guardant Health OMNI assay; CI calculated using Clopper-Pearson method. \*Focal amplification only. <sup>†</sup>Includes low shedders (no mutations detected, very low frequency mutations, or only variants of uncertain significance detected). amp, amplification; CI, confidence interval; INV, investigator; ISH, in situ hybridization; NE, not evaluable; ORR, objective response rate

encouraging survival outcomes in patients with gynecological tumors. Safety was consistent with the known profile. These data support T-DXd as a potential treatment for patients with gynecological HER2-expressing tumors who progressed on prior therapy.

## Plenary 03: Oral Abstract Presentations – Ovarian Cancer

### AS11. Ovarian cancer

P0008/#393

#### TIMED ADOPTIVE T-CELL THERAPY DURING CHEMOTHERAPY IN PLATINUM SENSITIVE RECURRENT EPITHELIAL OVARIAN CANCER, THE OVACURE PHASE I/II TRIAL

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**Introduction** T-cell infiltration correlates with epithelial ovarian cancer (EOC) survival, suggesting that EOC may be sensitive to ACT with autologous TIL. Carboplatin-paclitaxel (CP) chemotherapy lowers tumor induced immune-suppressive myeloid-cells, thereby creating a window-of-opportunity for TILs. IFN $\alpha$  may support the TIL.

**Methods** This phase I/II OVACURE trial (NCT04072263) studied the feasibility and safety of TIL during CP +/- IFN $\alpha$  in patients with recurrent platinum-sensitive EOC. Sixteen patients were enrolled. Patients received CP iv q3 weeks, 6x

and TIL iv 2 weeks after the 2<sup>nd</sup>, 3<sup>rd</sup> and 4<sup>th</sup> CP +/- IFN $\alpha$  12 weeks around the TIL infusion. CP +/- IFN $\alpha$  were used for lymphodepletion instead of IL-2. Patients who received 3 TIL cycles were evaluable. Secondary, signs of activity, immunomodulation, and T-cell reactivity were studied.

**Results** Fourteen patients were evaluable. Median age: 63 years (29–77), 13 HGSOC and 1 LGMOC. TIL could successfully be cultured for all patients. Addition of TIL during CP did not add toxicity, while additional IFN $\alpha$  resulted in grade 3 thrombocytopenia in the first 2 patients. Therefore, it was decided to continue treatment without IFN $\alpha$ . CP reduced plasma IL-6 levels and circulating myeloid-cell numbers. The optimal myeloid/lymphocyte ratio reduction was obtained 1–2 weeks after the 2<sup>nd</sup> CP. Interestingly, the platinum-free interval (PFI) exceeded the previous PFI after similar CP in 2 patients, including an ongoing PFI which increased from 8 to currently 43+ months.

**Conclusion/Implications** Combined treatment with CP chemotherapy and timed TIL did not increase toxicity and may result in clinical benefit for patients with EOC.