decreased white blood cell count (20.0%, 0, 33.3%), and anemia (20.0%, 1.9%, 13.3%). Dose discontinuation due to AEs occurred in 19.0%, 5.7%, and 0 pts, respectively. Treatment-related death was reported in two pts (1.9%) in cohort A (acute coronary syndrome, infection and sepsis).

Table: LBA44 Summary of efficacy

	Cohort A (n = 105)	Cohort B (n = 54)	Cohort C (n = 35)
BICR-assessed			
CR	9 (8.6)	3 (5.6)	—
PR	34 (32.4)	10 (18.5)	—
ORR	41.0 (31.5-51.0)	24.1 (13.5-37.6)	—
DCR	75.2 (65.9-83.1)	55.6 (41.4-69.1)	—
PFS (mo)	7.2 (6.1-12.4)	4.0 (2.1-6.1)	—
Investigator-assessed			
CR	4 (3.8)	2 (3.7)	1 (2.9)
PR	41 (39.0)	10 (18.5)	4 (11.4)
ORR	42.9 (33.2-52.9)	22.2 (12.0-35.6)	14.3 (4.8-30.3)
DCR	74.3 (64.8-82.3)	53.7 (39.6-67.4)	42.9 (26.3-60.7)
PFS (mo)	8.1 (6.2-12.4)	4.1 (2.1-5.1)	2.9 (2.0-6.2)
12-months OS rate	80.3 (70.7-87.0)	71.9 (55.8-83.0)	59.7 (40.9-74.3)

Conclusions: CAM plus FAM showed improved antitumor activity than CAM alone or investigator's choice of chemo in pts with R/M CC, with a tolerable safety profile.

Clinical trial identification: NCT04680988 (registered on December 23, 2020).

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LBA45 Overall survival (OS) outcomes from NRG-GY004, a phase III study comparing single-agent olaparib or combination cediranib and olaparib to platinum (Plat) based chemotherapy in recurrent plat sensitive ovarian cancer (OvCa)

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Background: In the NRG-GY004 (NCT02446600) primary analysis, neither olaparib (O) nor combined cediranib and olaparib (C+O) improved progression-free survival (PFS) compared to standard of care (SOC) plat therapy as treatment for relapsed plat sensitive ovca, although median PFS was longer in patients with gBRCAm (Liu et al., J Clin Oncol 2022). We now report the prespecified OS analysis.

Methods: Pts with plat sensitive high-grade serous or endometrioid, or BRCA-related, ovca were randomized 1:1:1 to SOC (carboplatin/paclitaxel; carboplatin/gemcitabine; or carboplatin/liposomal doxorubicin), O (300mg twice daily), or C+O (C 30mg daily + O 200mg twice daily), stratified by gBRCA status, PFI (6-12 vs >12 months), and prior anti-angiogenic therapy. OS was a secondary endpoint; analysis was specified to occur when at least 265 events had occurred cumulatively in the SOC and C+O arms.

Results: Between 4FEB2016 and 13NOV2017, 565 pts enrolled (187 SOC, 189 O, 189 C+O), and 528 pts initiated treatment (166 SOC, 183 O, 179 C+O). 23.7% of patients had gBRCAmt. Median follow-up was 66.5 months; 419 deaths had occurred. The hazard ratio (HR) for OS was 1.27 (95% CI 0.99-1.62, p = 0.06) between O and SOC and 1.12 (95% CI 0.87-1.43, p = 0.38) between C+O and SOC, with median OS of 32.7, 31.0, and 33.5 months for SOC, O, and C+O, respectively. In gBRCA pts, HR for OS was 1.39 (95% CI 0.80-2.42) for O vs SOC and 1.24 (95% CI 0.94-1.63) for C+O vs SOC, with median OS of 43.2, 41.3, and 44.8 mos for SOC, O, and C+O. In non-gBRCA pts, HR for these comparisons was 1.26 (95% CI 0.71-2.21) and 1.07 (0.82-1.40). 46 pts on SOC had non-protocol therapy before disease progression, including 36 pts receiving PARPi. 27.3% of pts on SOC, 7.9% on O, and 10.6% on C+O terminated OS follow-up early prior to death.

Conclusions: In NRG-GY004, neither O nor C+O improved OS compared to SOC as treatment for relapsed plat sensitive ovca. Hazard ratios for OS for both O and C+O exceeded 1 with wide 95% CIs that included 1. These findings must be interpreted with caution given the proportion of pts terminating follow-up early and the number of pts on the SOC arm who received off-protocol PARPi maintenance.

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