IGCS meeting abstracts

Plenary Sessions

Plenary 1

IGCS19-0523

1 **MILO/ENGOT-OV11: PHASE-3 STUDY OF BINIMETINIB VERSUS PHYSICIAN'S CHOICE CHEMOTHERAPY (PCC) IN RECURRENT OR PERSISTENT LOW-GRADE SEROUS CARCINOMAS OF THE OVARY, FALLOPIAN TUBE, OR PRIMARY PERITONEUM**

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Objectives Low-grade serous ovarian carcinomas (LGSOC) have historically low chemotherapy responses. Alterations affecting the MAPK pathway, most commonly KRAS/BRAF, are present in 30–60% of LGSOC. A phase II study of the MEK inhibitor selumetinib showed promising response rate of 15% in LGSOC and binimetinib, a potent MEK1/2 inhibitor, has demonstrated activity across multiple cancers.

Methods MILO (MEK-Inhibitor in Low-grade Serous Ovarian Cancer)/ENGOT-ov11 was an open-label, 2:1-randomized study of binimetinib (45-mg BID) vs PCC in LGSOC. Eligible patients had recurrent or persistent measurable LGSOC following ≥1 prior platinum-based chemotherapy, ≤3 prior chemotherapy lines, and no prior MEK-or BRAF-inhibitor. The primary endpoint was progression-free survival (PFS) by blinded central review; additional assessments: overall survival (OS), overall response rate (ORR), duration of response (DOR), clinical-benefit rate, biomarkers, and safety. (NCT01849874).

Results 303 patients were randomized (201 binimetinib,102 PCC). Median PFS was 9.1 months (95% CI:7.3,11.3) for binimetinib and 10.6 months (95% CI:9.2,14.5) for PCC (HR:1.21(0.79,1.86);closed early for futility). Secondary efficacy endpoints were similar in the two groups: ORR 16% (complete/partial responses[CR/PRs]=32) vs 13%(CR/PRs=13); median DOR 8.1 (range:0.3–12.0+ months) vs 6.7 (0.3–9.7+ months); and median OS 25.3 vs 20.8 months, for binimetinib and PCC, respectively. Safety results were consistent with known safety profile of binimetinib; most common ≥grade 3 events were blood CK increased(20%) and hypertension(20%). Post-hoc analysis suggests a possible association between KRAS mutation and response to binimetinib.

Conclusions Although MILO did not meet its primary endpoint, binimetinib showed activity in LGSOC across the efficacy endpoints evaluated. Chemotherapy responses were higher than predicted. Further evaluation is warranted.

IGCS19-0455

2 **EXPLORATORY ANALYSIS OF POSTPROGRESSION AND PATIENT-CENTERED OUTCOMES IN ARIEL3: A PHASE 3, RANDOMIZED, PLACEBO-CONTROLLED STUDY OF RUCAPARIB MAINTENANCE TREATMENT IN PATIENTS WITH RECURRENT OVARIAN CARCINOMA**

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Objectives In ARIEL3, rucaparib maintenance treatment significantly improved progression-free survival (PFS) vs placebo. A prespecified exploratory analysis investigated postprogression outcomes. Additionally, a post hoc exploratory analysis investigated patient-centered outcomes during rucaparib maintenance treatment.

Methods Patients were randomized 2:1 to receive oral rucaparib (600 mg BID) or placebo. Postprogression endpoints included time to start of first subsequent therapy (TFST), time to second investigator-assessed PFS or death (PFS2), and time to start of second subsequent therapy (TSST); overall survival data are not yet mature. Patient-centered outcomes included quality-adjusted