813MO Efficacy of subsequent chemotherapy for patients with BRCA1/2 mutated platinum-sensitive recurrent epithelial ovarian cancer (EOC) progressing on olaparib vs placebo: The SOLO 2/ENGOT Ov-21 trial

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Background: SOLO2 (ENGOT Ov-21; NCT01874353) demonstrated that maintenance olaparib (O) in patients (pts) with platinum-sensitive relapsed EOC and a *BRCA1/2* mutation led to clinically significant survival benefit. We report on the efficacy of subsequent chemotherapy at the time of disease progression.

Methods: First subsequent treatment was analysed in pts who progressed according to RECIST1.1 in the O and placebo (P) arms. We conducted a post-hoc analysis of time to second progression (TTSP) calculated from the date of RECIST progression after O maintenance to next progression or death as a surrogate of first post-olaparib treatment progression-free survival.

Results: 106/195 (54%) and 80/99 (81%) pts had a RECIST progression in the O and P arms respectively. Pt baseline demographics were balanced between both arms. Overall, 161/186 (87%) pts received a first subsequent therapy, including a chemotherapy in 150/161 (93%) and a PARP inhibitor in 29/161 (18%, all in the P arm). In the P arm, 33/75 (44%) and 42/75 (56%) pts received a non-platinum and a platinum-based chemotherapy respectively vs 32/86 (37%) and 54/86 (63%) in the O arm. Overall, in pts receiving subsequent treatment, TTSP was longer in the placebo compared to the O arm: 11.1 vs 7 months (HR 1.93; 95% CI [1.35-2.76]). TTSP was 14.3 vs 7m with platinum-based chemotherapy and 8.3 vs 5.5m with non-platinum chemotherapy in the P and O arm respectively.

Conclusions: In this SOLO2 post-hoc comparison, some degree of resistance to standard subsequent platinum and non-platinum chemotherapy is noted in the O arm. However, the TTSP reduction being not at the expense of overall survival, it suggests that the earlier use of O remains optimal in this population. The best post O management should be studied in prospective manner.

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814MO Phase II study of olaparib (O) plus durvalumab (D) and bevacizumab (B) (MEDIOLA): Initial results in patients (pts) with non-germline BRCA-mutated (non-gBRCAm) platinum sensitive relapsed (PSR) ovarian cancer (OC)

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Background: Olaparib is a PARP inhibitor approved in first-line and recurrent OC. Results of O+D in gBRCAm PSR OC have been presented. MEDIOLA (NCT02734004) then evaluated combining O+D (doublet cohort) or O+D+B (triplet cohort) in non-gBRCAm PSR OC. Here we present initial results.

Methods: Pts had confirmed non-gBRCAm PSR OC and had progressed after receiving 1−2 prior lines (L) of platinum-based chemotherapy. Pts received O 300 mg bid and D 1.5g IV q4 weeks (w) and B 10 mg/kg q2w (triplet only) until progressive disease. Tumours were assessed by RECIST v1.1 at baseline and q8w. Primary endpoints were safety and 24-w disease control rate (DCR). Secondary endpoints included objective response rate (ORR), median duration of response (mDOR) and progression-free survival (PFS).

Results: From Nov 2018 to Feb 2019, 32 pts (69% 2nd L) enrolled and received O+D; from May 2018 to Jan 2019, 31 (68% 2nd L) enrolled and received O+D+B. At the data cut-off 13 Feb 2020, 22% of O+D and 42% of O+D+B pts remained on treatment. The most common grade $\geq$3 AEs in O+D were anaemia, lipase increased and neutropenia and anaemia, hypertension, fatigue, lipase increased, and neutropenia in O+D+B. Two (6%) and five (16%) pts discontinued one or more study drug due to an AE in O+D and O+D+B, respectively. Efficacy is summarized in the table. Efficacy in biomarker

subgroups, including by presence of genome-wide loss of heterozygosity, will be presented.

Table: 814MO

Non-gBRCAm PSR OC	Doublet cohort (O+D) n = 32	Triplet cohort (O+D+B) n = 31
24-w DCR, %	28.1% (90% CI 15.5–43.9)	77.4% (90% CI 61.7–88.9)
Confirmed ORR, %	31.3% (95% CI 16.1–50.0)	77.4% (95% CI 58.9–90.4)
Median confirmed DOR (mo)	6.9 (IQR 5.7–11.1)	11.1 (IQR 9.0–16.4)
Median PFS (mo)	5.5 (95% CI 3.6–7.5)	14.7 (95% CI 10.0–18.1)

CI, confidence interval; IQR, interquartile range.

Conclusions: Combining O+D and O+D+B was well tolerated in pts with non-gBRCAm PSR OC, consistent with the known safety profiles of the single agents. The DCR for the doublet cohort did not meet the prespecified target of 80%. The 95% CI for DCR in the triplet cohort included the prespecified target of 80%. ORR and PFS in the triplet cohort demonstrate promising activity in non-gBRCAm PSR OC, and in this group the ORR and PFS are higher than reported for single-agent PARP or VEGF inhibitors.

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815MO The impact of chemosensitivity assessed by modeled CA-125 KELIM on the likelihood of long progression-free survivorship (PS) after 1st line treatment in ovarian cancer: An analysis of 4,450 patients

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Background: Primary tumor chemosensitivity plays an important but poorly understood role in the ovarian cancer patient prognosis. The modeled CA-125 kinetic parameter (KELIM) is an indicator of chemosensitivity, and is associated with survival (*Clin Cancer Res* 2019 & 2020; *JNCI CS* 2020). The objective was to assess the role of KELIM regarding the probability of long progression-free survivorship (PS) > 5 years after 1st line treatment.

Methods: The datasets from 3 phase III trials in adjuvant setting (AGO-OVAR 9; AGO-OVAR 7 and ICON 7) were analyzed to explore the prognostic role of KELIM regarding the probability of PS in 2,868 stage (st) I-IV patients. An independent population-based cohort of 1,582 st II-IV patients in neo-adjuvant setting from The Netherlands Cancer Registry (NCR) was used as a validation dataset.

Results: Of 2,868 patients in the learning set (median 45-month follow-up), 82 patients (2.8%) were PS: 48 st I-II (PS probability (PSp) = 9.5%); 32 st III (PSp = 1.6%); 2 st IV (PSp = 0.5%). With favorable KELIM > 0.06 days-1, PSp increased to 12.0% for st I-II, 2.9% for st III & 2.1% for st IV. In multivariable logistic regression, higher FIGO stage (st I-II reference; st III, OR = 0.18 and st IV: OR = 0.06) and KELIM (OR = 2.35 [1.51-3.59]) were predictors of PS. Of 1,582 patients in the NCR dataset (median 95-month follow-up), 36 patients (2.7%) were PS: 2 st II (PSp = 22.2%); 26 st III (PSp = 2.8%); 8 st IV (PSp = 1.2%). With favorable KELIM, PSp increased to 5.4% for st III, and 2.4% for st IV. In multivariable regression, completeness of interval debulking surgery (OR = 6.25 [2.40-21.41]) and KELIM (OR = 3.82 [1.49-9.65]) were predictors of PS. PSp was 12% for st III with favorable KELIM and complete surgery. In an explorative set with 509 patients, the KELIM prognostic impact was more marked in BRCA wild-type and BRCA1 mutated patients, than in BRCA2.

Conclusions: KELIM is an independent prognostic factor of progression-free survivorship > 5 years after 1st line treatment. The PSp is doubled in patients with favorable KELIM. The respective impacts of chemosensitivity and surgery relative to chance of potential cure are better understood.

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