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CLINICAL AND MOLECULAR CHARACTERISTICS OF ARIEL3 PATIENTS WHO DERIVED EXCEPTIONAL BENEFIT FROM RUCAPARIB MAINTENANCE TREATMENT FOR HIGH-GRADE OVARIAN CANCER (HGOC)

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Objectives ARIEL3 is a placebo-controlled randomized trial of the PARP inhibitor (PARPi) rucaparib as maintenance treatment in HGOC patients who responded to the latest line of platinum therapy (NCT01968213). Rucaparib improved progression-free survival (PFS) across all predefined subgroups. Here, we present an exploratory analysis of characteristics associated with exceptional benefit from rucaparib.

Methods Patients were randomized 2:1 to rucaparib 600 mg BID or placebo. As of 31 Dec 2019 (data cutoff), 33/375 (9%) and 1/189 (0.5%) patients were still ongoing and receiving rucaparib or placebo. Molecular features (genomic alterations, BRCA1 promoter methylation) and baseline clinical

characteristics were compared between patients who derived exceptional benefit (PFS ≥ 2 yrs), and those with disease progression on first scan (≈ 12 wks; the short-term subgroup) within each treatment arm.

Results of 564 patients, 79/375 (21%) in the rucaparib arm and 4/189 (2%) in the placebo arm showed exceptional benefit. Within the rucaparib arm, exceptional benefit patients had more favorable clinical prognostic factors at baseline versus the short-term subgroup (Table). Although BRCA mutations were enriched in the rucaparib exceptional benefit subgroup, 33/79 (42%) of these patients were BRCA wild type. Patterns of enrichment varied among other biomarkers. Overall trends were similar in the placebo arm.

Conclusions Exceptional benefit in ARIEL3 was more common in, but not exclusive to, patients with favorable clinical characteristics and known mechanisms of PARPi sensitivity. Our results suggest rucaparib can deliver exceptional benefit to a diverse set of patients with HGOC.

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EFFICACY AND SAFETY OF NIRAPARIB MAINTENANCE TREATMENT IN PLATINUM-SENSITIVE RECURRENT OVARIAN CANCER AFTER SHORTER OR LONGER CHEMOTHERAPY: A POST HOC SUBGROUP ANALYSIS

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Objectives Traditionally ≥ 6 cycles of platinum-containing chemotherapy (Pt-chemo) are recommended for platinum-sensitive recurrent ovarian cancer (PSROC). PARP inhibitor maintenance treatment (MT) can be initiated upon clinical complete/partial response (CR/PR) after ≥ 4 cycles of chemotherapy. Shorter chemotherapy may improve patient experience without compromising efficacy. This study aims to compare the efficacy and safety of niraparib to placebo as MT administered after ≤ 4 or > 4 cycles of Pt-chemo.

Abstract 0016/#233 Table 1

	Rucaparib (N=375)			Placebo (N=189)		
Baseline characteristics	Exceptional benefit n=79	Short-term subgroup n=64	Odds ratio (95% CI)	Exceptional benefit n=4	Short-term subgroup n=62	Odds ratio (95% CI)
No measurable disease	58 (73%)	26 (41%)	4.0 (2.0-8.0) ^a	3 (75%)	33 (53%)	2.6 (0.4-35.3)
Complete response to latest platinum	31 (39%)	13 (20%)	2.5 (1.2-5.3) ^a	1 (25%)	11 (18%)	1.5 (0.1-11.2)
Penultimate platinum-free interval > 12 mo	55 (70%)	30 (47%)	2.6 (1.3-5.2) ^a	4 (100%)	29 (47%)	NA
BRCA mutation	46 (58%)	12 (19%)	6.0 (2.8-13.3) ^a	3 (75%)	25 (40%)	4.4 (0.6-59.0)
BRCAwt/LOH-high	18 (23%)	19 (30%)	0.7 (0.3-1.5)	0	14 (23%)	NA
BRCAwt/LOH-low	8 (10%)	28 (44%)	0.14 (0.1-0.4) ^a	1 (25%)	16 (26%)	1.0 (0.1-6.8)
BRCAwt + RAD51C/D mutation ^b	6 (8%)	0	NA	0	0	NA
BRCAwt + high BRCA1 promoter methylation ^c	6/25 (24%)	7/47 (15%)	1.8 (0.5-6.0)	0/1	5/29 (17%)	NA

BRCAwt, BRCA wild type; LOH, loss of heterozygosity; NA, not applicable

^aSignificant result; ^bP=0.033 (Fisher's exact test); ^ccln samples with known methylation status