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Overall Survival Results From ARIEL3: A Phase 3 Randomised, Double-blind Study of Rucaparib vs Placebo Following Response to Platinum-Based Chemotherapy for Recurrent Ovarian Carcinoma

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Disclosure

Company name	*Honoraria/ expenses*	*Consulting/ advisory board*	*Funded research*	*Royalties/ patent*	*Stock options*	*Ownership/ equity position*	*Employee*	*Other (please specify)*
Clovis Oncology, Abbvie, Immunogen, Merck, Genmab			X					X (travel/accommodations/expenses)
Clovis Oncology, Abbvie, Agenus, Alkermes, Genmab, Gradalis, Novocure, Oncxerna, GSK, Immunogen, Merck, AstraZeneca, Genentech/Roche, GOG-Foundation, Genelux, Zentalis, Eisai		X						
Research to Practice, Vaniam Group	X							X (travel/accommodations/expenses)
US Oncology Research							X	

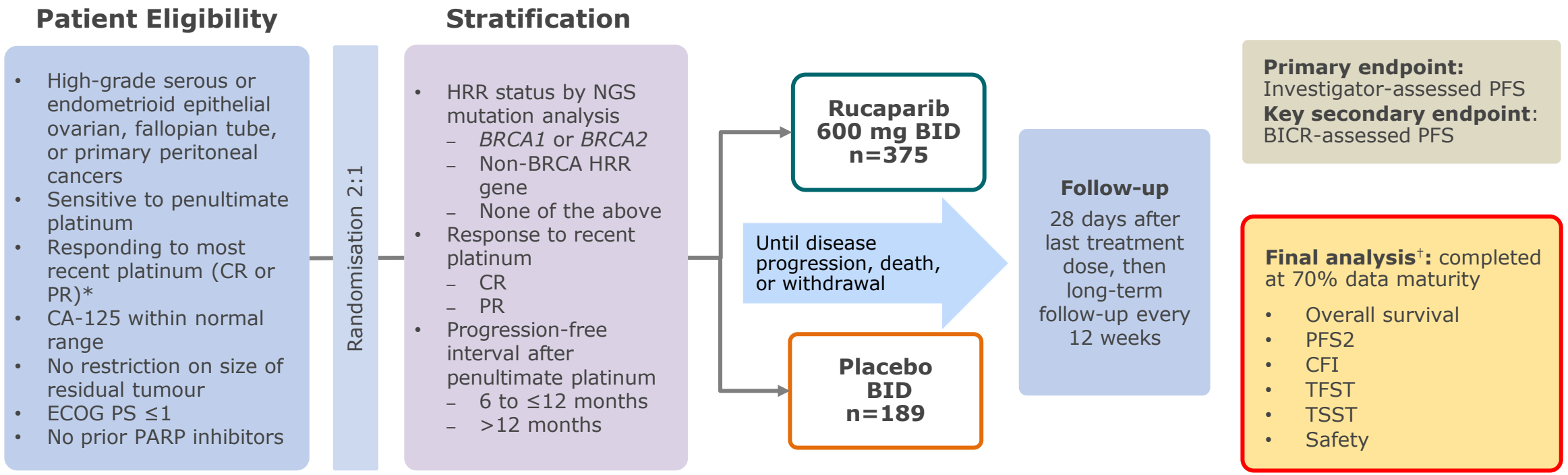
Background

- Rucaparib is a PARP inhibitor that is approved in the US and Europe for the maintenance therapy of patients with recurrent ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based therapy[1,2]
- In the phase 3, randomised, double-blind, placebo-controlled ARIEL3 trial (NCT01968213), rucaparib maintenance therapy significantly improved PFS and post-progression outcomes (PFS2, CFI, TFST, TSST) vs placebo in patients with platinum-sensitive ovarian cancer[3,4]
- We present final OS results, updated post-progression outcomes, and updated safety from ARIEL3

CFI, chemotherapy-free interval; OS, overall survival; PARP, poly(ADP-ribose) polymerase; PFS, progression-free survival; PFS2, PFS on the subsequent line of therapy; TFST, time to start of first subsequent therapy; TSST, time to start of second subsequent therapy.

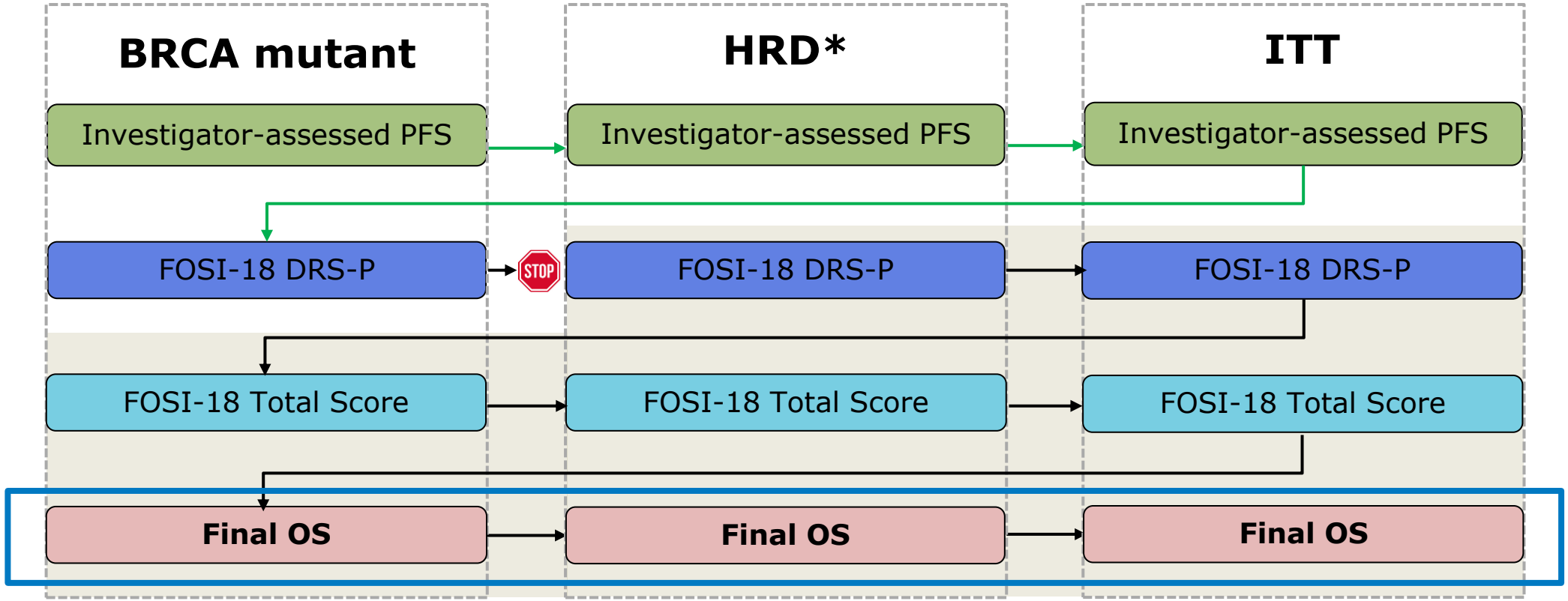
1. Rubraca® (rucaparib) tablets [prescribing information]. Boulder, CO: Clovis Oncology, Inc.; 2022. 2. Rubraca® (rucaparib) tablets [summary of product characteristics]. Swords, Ireland: Clovis Oncology Ireland Ltd.; 2022. 3. Coleman et al. *Lancet*. 2017;390:1949-61. 4. Ledermann et al. *Lancet Oncol*. 2020;21:710-22.

ARIEL3 Study Design



A hypothesis of superiority in overall survival was not prespecified in the protocol/study design.
*CR (defined by RECIST) or PR (defined by RECIST and/or a GCIG CA-125 response [CA-125 within normal range]) maintained until entry to ARIEL3 (≤8 weeks from last dose of chemotherapy). †Analyses were done for the molecularly defined nested cohorts (BRCA mutant, HRD, and ITT), and exploratory analyses were done in the non-nested subgroups of patients with BRCA wild-type carcinoma.
BICR, blinded independent central review; BID, twice daily; BRCA, *BRCA1* and *BRCA2;* CA-125, cancer antigen 125; CFI, chemotherapy-free interval; CR, complete response; ECOG PS, Eastern Cooperative Oncology Group performance status; GCIG, Gynecological Cancer InterGroup; HRD, homologous recombination deficiency; HRR, homologous recombination repair; NGS, next-generation sequencing; PARP, poly(ADP-ribose) polymerase; PD, progressive disease; PFS, progression-free survival; PFS2, PFS on the subsequent line of therapy; PR, partial response; RECIST, Response Evaluation Criteria In Solid Tumours version 1.1; TFST, time to start of first subsequent therapy; TSST, time to start of second subsequent therapy.

ARIEL3 Step-down Analysis



- No statistical significance was observed in the first secondary endpoint of time to worsening in the FOSI-18 DRS-P subscale in the BRCA mutant cohort[1]; therefore, no further statistical significance of subsequent endpoints can be claimed

*Includes BRCA-mutant and BRCA–wild-type/LOH-high groups.
BRCA, *BRCA1* and *BRCA2*; DRS-P, disease related symptom-physical subscale; FOSI-18, FACT-Ovarian Symptom Index-18; HRD, homologous recombination deficiency; ITT, intent-to-treat; OS, overall survival; PFS, progression-free survival.
1. Coleman et al. *Lancet*. 2017;390:1949-61.

Patient Disposition

	Rucaparib	Placebo
Randomized, % (n)	**100 (375)**	**100 (189)**
Treated, % (n)	**99.2 (372)**	**100 (189)**
Ongoing, % (n)*	**4.0 (15)**	**0**
Discontinued, % (n)†	**96.0 (360)**	**100 (189)**
Disease progression	**69.4 (250)**	**92.1 (174)**
Clinical progression	**3.1 (11)**	**3.2 (6)**
Adverse event	18.1 (65)	0.5 (1)
Withdrew consent‡	5.0 (18)	3.2 (6)
Investigator decision	1.1 (4)	0 (0)
Other§	3.3 (12)	1.1 (2)

- Median duration of follow-up was 6.4 years for rucaparib and 6.4 years for placebo

Data cutoff date: 4 April 2022.
*All patients remaining on treatment after the data cutoff date transitioned to receiving rucaparib via other access mechanisms. †Percentages in subcategories are based on the number of patients who discontinued study drug. ‡Includes categories of patient withdrew consent and withdrew consent for treatment only. §Includes categories of pregnancy, study terminated by sponsor, unknown, noncompliance, and other.

Summary of Subsequent Therapy

	BRCA mutant		HRD*		ITT	
	Rucaparib (n=130)	Placebo (n=66)	Rucaparib (n=236)	Placebo (n=118)	Rucaparib (n=375)	Placebo (n=189)
Patients without subsequent anticancer therapy, % (n)	**27.7 (36)**	**9.1 (6)**	**23.7 (56)**	**11.0 (13)**	**21.9 (82)**	**11.1 (21)**
Disposition of patients, % (n)†						
Ongoing	19.4 (7)	0	25.0 (14)	0	18.3 (15)	0
Died	30.6 (11)	33.3 (2)	26.8 (15)	38.5 (5)	31.7 (26)	38.1(8)
Other‡	50.0 (18)	66.7 (4)	48.2 (27)	61.5 (8)	50.0 (41)	61.9 (13)
Patients with ≥1 subsequent anticancer therapy, % (n)	**72.3 (94)**	**90.9 (60)**	**76.3 (180)**	**89.0 (105)**	**78.1 (293)**	**88.9 (168)**
No. subsequent regimens, % (n)§						
1	22.3 (21)	23.3 (14)	20.0 (36)	19.0 (20)	19.1 (56)	20.2 (34)
2	30.9 (29)	16.7 (10)	26.1 (47)	19.0 (20)	25.9 (76)	22.0 (37)
3	18.1 (17)	13.3 (8)	18.9 (34)	17.1 (18)	20.5 (60)	17.3 (29)
≥4	28.7 (27)	46.7 (28)	35.0 (63)	44.8 (47)	34.5 (101)	40.5 (68)
Median, No. (range)	2 (1–8)	3 (1–8)	3 (1–8)	3 (1–8)	3 (1–10)	3 (1–8)
Patients with subsequent PARP inhibitor containing regimen, % (n)§	**34.0 (32)**	**71.7 (43)**	**27.2 (49)**	**59.0 (62)**	**20.8 (61)**	**45.8 (77)**

Data cutoff date: 4 April 2022.
*Includes BRCA-mutant and BRCA wild-type/LOH-high groups. †Percentages are based on the number of patients without subsequent treatment reported. ‡Includes categories of withdrew consent, missing subsequent treatment data, discontinued on study but rolled over to receive treatment through rucaparib access programs or other mechanisms. §Percentages are based on the number of patients with subsequent treatment reported.
BRCA, *BRCA1* and *BRCA2*; HRD, homologous recombination deficiency; ITT, intent-to-treat; LOH, loss of heterozygosity; PARP, poly(ADP-ribose) polymerase.

Subsequent PARP Inhibitors in Patients Treated With Placebo

	BRCA mutant	Non-nested BRCA wild-type/ LOH high	Non-nested BRCA wild-type/ LOH low
	Placebo (n=66)	**Placebo (n=52)**	**Placebo (n=54)**
At least 1 subsequent treatment for ovarian cancer, % (n)	90.9 (60)	86.5 (45)	90.7 (49)
≥1 subsequent PARP inhibitor containing regimen, % (n)	**71.7 (43)**	**42.2 (19)**	**20.4 (10)**
Time to start of first PARP inhibitor,* median, mo (95% CI)	14.1 (11.6–16.7)	21.0 (15.8–28.1)	22.8 (8.8–31.8)
First subsequent PARP inhibitor duration, median, mo (95% CI)	13.8 (8.6–17.0)	9.2 (4.0–42.9)	9.0 (1.5–20.5)
Total subsequent PARP inhibitor duration, median, mo (95% CI)	16.5 (11.0–19.7)	9.2 (4.0–45.1)	9.0 (1.5–20.5)

Data cutoff date: 4 April 2022.
*From date of randomisation.
BRCA, *BRCA1* and *BRCA2*; CI, confidence interval; LOH, loss of heterozygosity; mo, months; PARP, poly(ADP-ribose) polymerase.

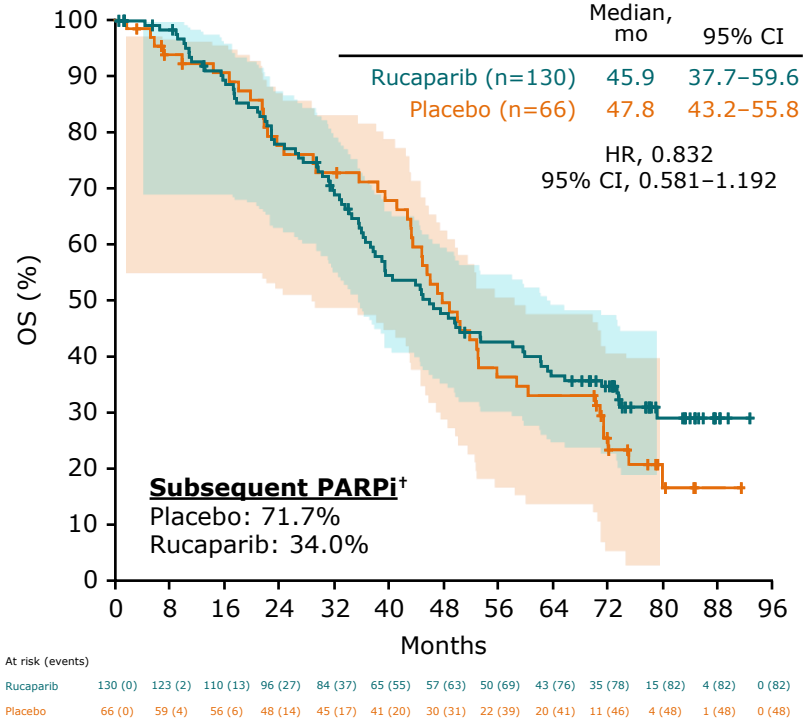
Subsequent PARP Inhibitors in Patients Treated With Placebo

	BRCA mutant	Non-nested BRCA wild-type/ LOH high	Non-nested BRCA wild-type/ LOH low
	Placebo (n=66)	**Placebo (n=52)**	**Placebo (n=54)**
At least 1 subsequent treatment for ovarian cancer, % (n)	90.9 (60)	86.5 (45)	90.7 (49)
≥1 subsequent PARP inhibitor containing regimen, % (n)	71.7 (43)	42.2 (19)	20.4 (10)
Time to start of first PARP inhibitor,* median, mo (95% CI)	**14.1 (11.6–16.7)**	**21.0 (15.8–28.1)**	**22.8 (8.8–31.8)**
First subsequent PARP inhibitor duration, median, mo (95% CI)	**13.8 (8.6–17.0)**	**9.2 (4.0–42.9)**	**9.0 (1.5–20.5)**
Total subsequent PARP inhibitor duration, median, mo (95% CI)	16.5 (11.0–19.7)	9.2 (4.0–45.1)	9.0 (1.5–20.5)

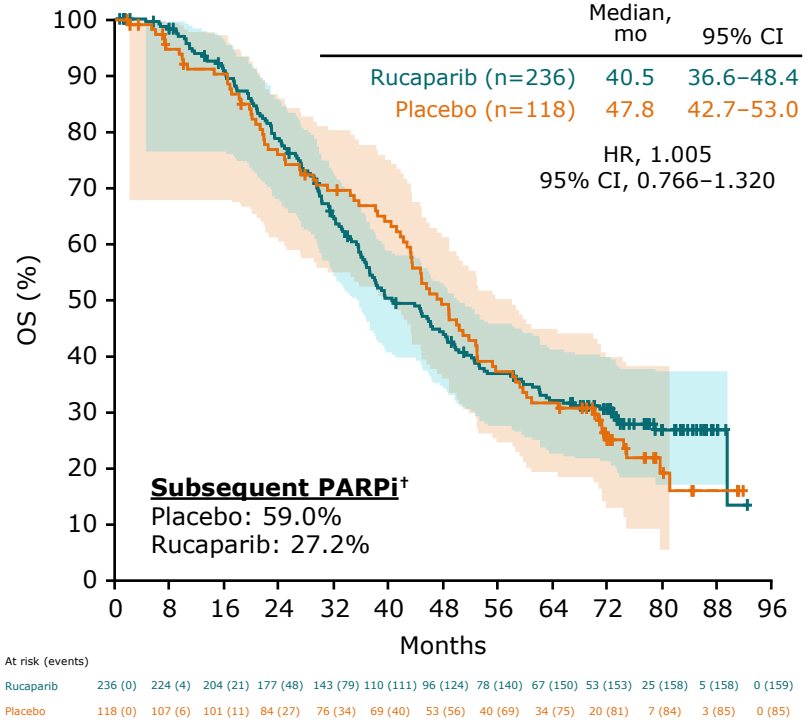
Data cutoff date: 4 April 2022.
*From date of randomisation.
BRCA, *BRCA1* and *BRCA2*; CI, confidence interval; LOH, loss of heterozygosity; mo, months; PARP, poly(ADP-ribose) polymerase.

Final OS: Nested Cohorts

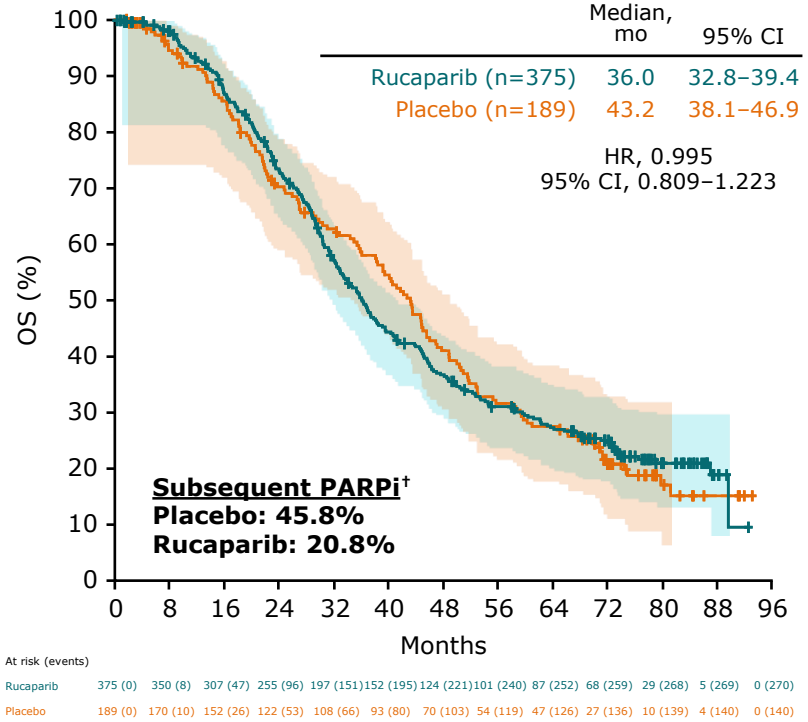
BRCA-Mutant Cohort



HRD Cohort*



ITT Population

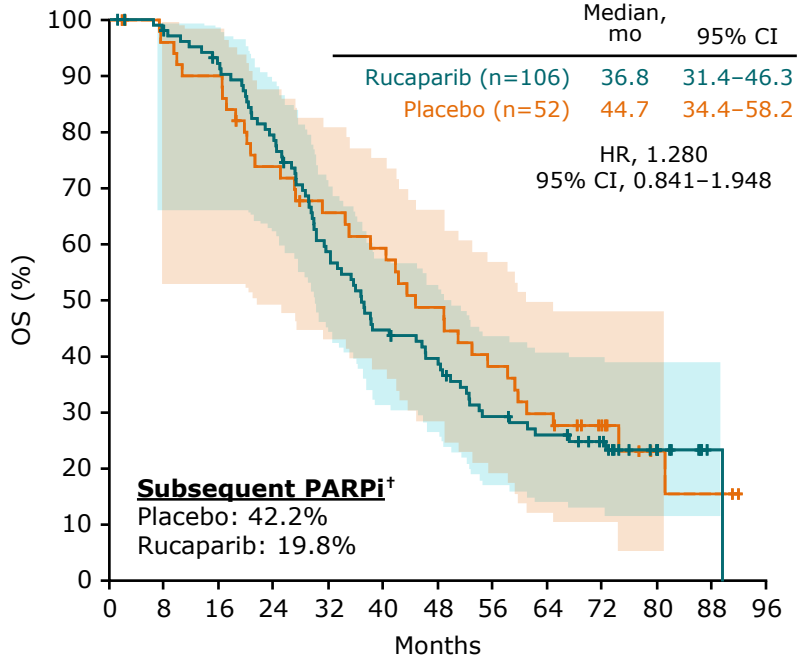


- Nearly half (45.8%) of patients randomised to the placebo group received subsequent PARP inhibitor therapy

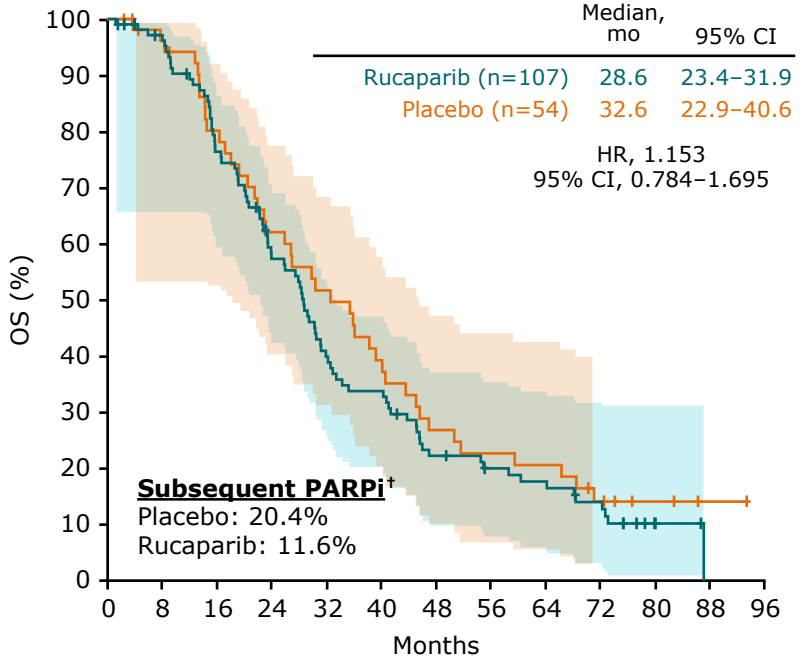
Data cutoff date: 4 April 2022.
*Includes BRCA-mutant and BRCA–wild-type/LOH-high groups. †Patients receiving a PARP inhibitor during any subsequent treatment.
BRCA, *BRCA1* and *BRCA2*; CI, confidence interval; HR, hazard ratio; HRD, homologous recombination deficiency; ITT, intent-to-treat; LOH, loss of heterozygosity; mo, months; OS, overall survival; PARPi, poly(ADP-ribose) polymerase inhibitor.

Final OS: BRCA Wild-Type, Non-Nested Cohorts

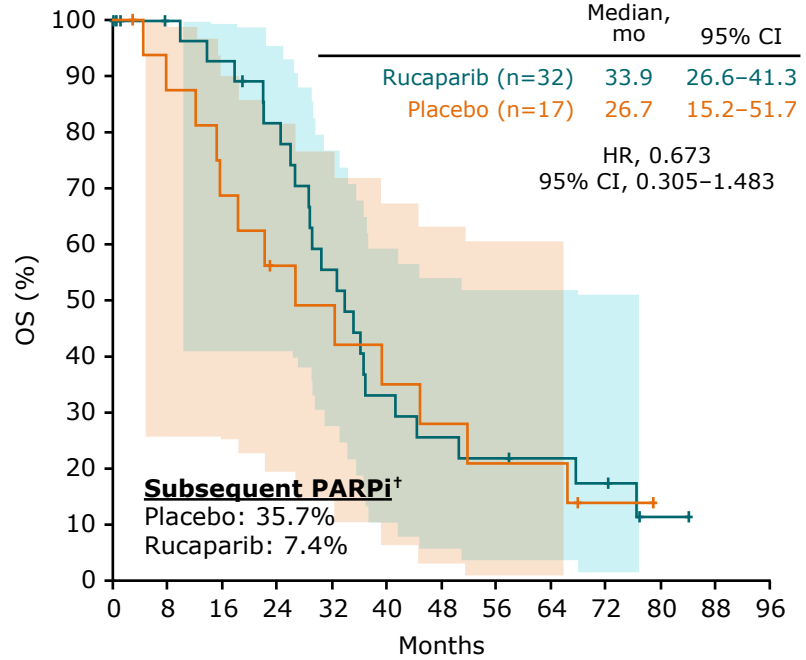
BRCA Wild-Type/LOH High



BRCA Wild-Type/LOH Low

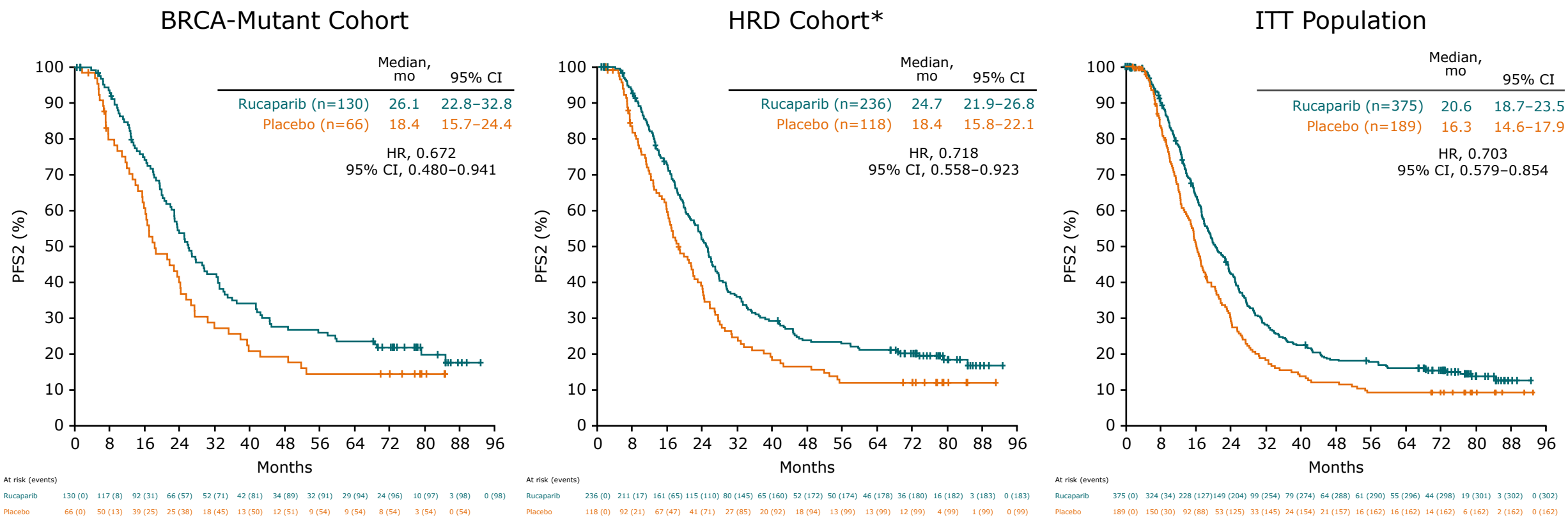


BRCA Wild-Type/LOH Unknown



Data cutoff date: 4 April 2022.
†Patients receiving a PARP inhibitor during any subsequent treatment.
BRCA, *BRCA1* and *BRCA2*; CI, confidence interval; HR, hazard ratio; LOH, loss of heterozygosity; mo, months; OS, overall survival; PARPi, poly(ADP-ribose) polymerase inhibitor.

Post-progression Outcomes: PFS2 (Nested Cohorts)

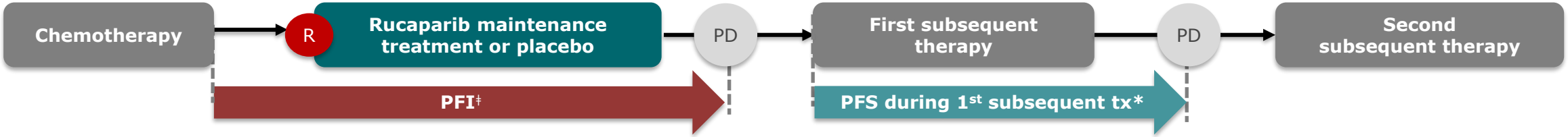


- Post-progression outcomes (PFS2, CFI, TFST, TSST) were similar to those previously reported at a data cutoff of December 31, 2017[1]

Data cutoff date: 4 April 2022.
*Includes BRCA-mutant and BRCA–wild-type/LOH-high groups.
BRCA, *BRCA1* and *BRCA2*; CFI, chemotherapy-free interval; CI, confidence interval; HR, hazard ratio; HRD, homologous recombination deficiency; ITT, intent-to-treat; LOH, loss of heterozygosity; mo, months; PFS2, progression-free survival on the subsequent line of therapy; TFST, time to start of first subsequent therapy; TSST, time to start of second subsequent therapy.

1. Ledermann et al. *Lancet Oncol*. 2020;21:710-22.

Exploratory Analysis of PFS During First Subsequent Platinum-Based Chemotherapy



	ITT Population			PFI <6 months			PFI 6–≤12 months			PFI >12 months		
	Event rate	Median, mo (95% CI)	Log-rank *P* value	Event rate	Median, mo (95% CI)	Log-rank *P* value	Event rate	Median, mo (95% CI)	Log-rank *P* value	Event rate	Median, mo (95% CI)	Log-rank *P* value
Rucaparib	163/174	7.0 (6.2–7.8)	<0.0001	30/30	5.4 (2.8–7.7)	0.2139	58/61	7.4 (6.1–8.6)	0.0056	75/83	7.1 (6.2–9.7)	0.0017
Placebo	61/76	11.3 (9.9–14.1)		14/16	8.3 (3.3–10.9)		38/46	11.3 (9.4–14.4)		9/14	18.5 (10.3–NA)	

- In the ITT population, 9.2% of patients in the rucaparib group and 25.0% in the placebo group received a PARP inhibitor maintenance therapy following their first subsequent platinum-based chemotherapy

Data cutoff date: 4 April 2022.
*Progression free survival from the start of first subsequent therapy to disease progression. ‡From date of last chemotherapy prior to randomisation to date of PD on ARIEL3 treatment. CI, confidence interval; ITT, intent-to-treat; mo, months; NA, not applicable; PD, disease progression; PFI, progression-free interval; PFS, progression-free survival; R, randomisation.

Summary of Safety

	Rucaparib (n=372)		Placebo (n=189)	
% (n)	Primary	Final	Primary	Final
Any-grade TEAE	100 (372)	100 (372)	96.3 (182)	96.3 (182)
Grade ≥3 TEAE	56.2 (209)	62.6 (233)	14.8 (28)	16.4 (31)
Treatment interruption due to TEAE	63.7 (237)	67.5 (251)	10.1 (19)	10.1 (19)
Dose reduction due to TEAE	54.6 (203)	56.2 (209)	4.2 (8)	4.2 (8)
Discontinuation due to TEAE*	13.4 (50)	20.2 (75)	1.6 (3)	2.1 (4)
Deaths due to TEAE	1.6 (6)	2.4 (9)	1.1 (2)	1.1 (2)

- The median duration of treatment was 8.3 months (range, 0–89) for the rucaparib group and 5.5 months (range, 0–91) for the placebo group
- MDS/AML was reported in 3.8% (n=14) of patients in the rucaparib group and 3.2% (n=6) of patients in the placebo group (*P*=0.72; reported poststudy drug treatment in 8 cases in the rucaparib group and 6 in the placebo group)[†]
- Safety was consistent with prior reports[1,2]

Data cutoff date for safety data: 4 April 2022. *Excluding disease progression. [†]Data cutoff date for MDS/AML: 23 March 2022.
AML, acute myeloid leukemia; MDS, myelodysplastic syndrome; TEAE, treatment-emergent adverse event.
1. Coleman et al. *Lancet*. 2017;390:1949-61. 2. Ledermann et al. *Lancet Oncol*. 2020;21:710-22.

Conclusions

- These data support the use of rucaparib as a maintenance therapy for recurrent platinum-sensitive ovarian carcinoma
- Although no OS benefit was seen, the PFS benefit for rucaparib was maintained through the subsequent line of therapy
  - OS data were confounded by an imbalance and potential selection bias of subsequent treatments, including PARP inhibitors, both of which could not be controlled for post-trial
  - ARIEL3 was not designed to control for the selection of subsequent treatments post-progression
- Rucaparib's safety and tolerability profile remains consistent with prior reports[1,2] based on long-term follow-up
- As reported with other PARP inhibitors[3], these results add further evidence that the efficacy of subsequent platinum-based chemotherapy may be diminished following progression on PARP inhibitor maintenance treatment
  - The effect of various subsequent therapies on OS and overlapping mechanisms of resistance between platinum and PARP inhibitors is under further investigation

OS, overall survival; PARP, poly(ADP-ribose) polymerase; PFS, progression-free survival.

1. Coleman et al. *Lancet*. 2017;390:1949-61. 2. Ledermann et al. *Lancet Oncol*. 2020;21:710-22;
3. Frenel et al. Ann Oncol. 2022; S0923-7534(22)01740-9.

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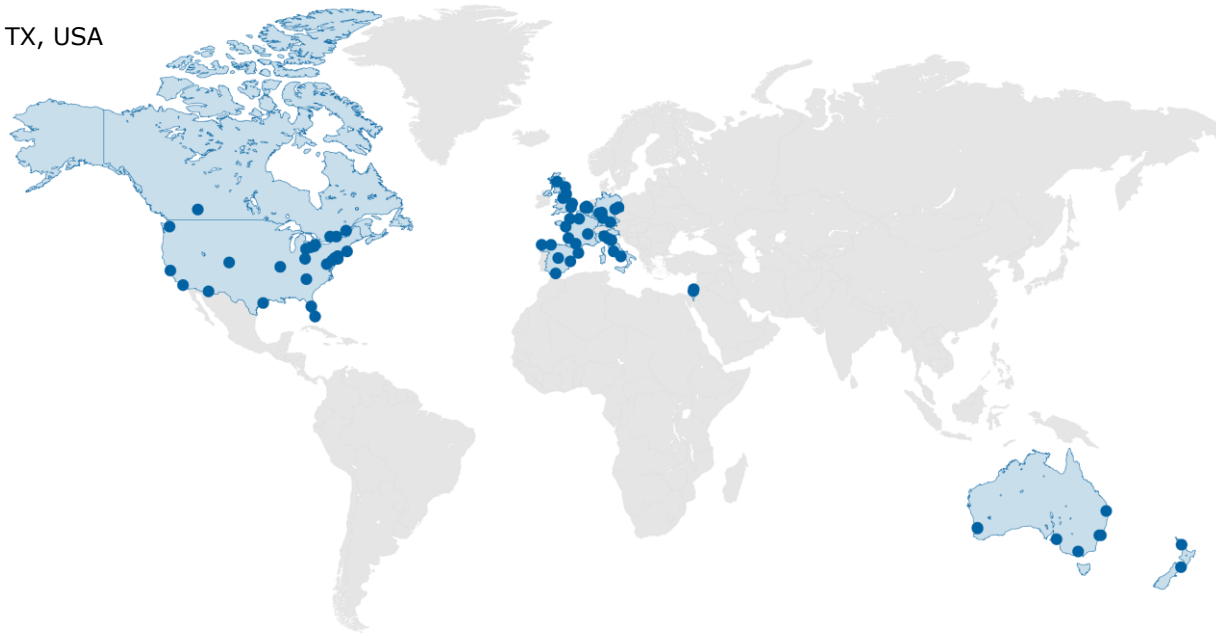

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