Effect of Prior Bevacizumab Therapy in Patients with Platinum-Sensitive Recurrent Ovarian Carcinoma in the Phase 3 Study ARIEL3

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IGCS INTERNATIONAL GYNECOLOGIC CANCER SOCIETY

FACULTY DISCLOSURE

	No, nothing to disclose
X	Yes, please specify:

Company Name	*Honoraria/ Expenses*	*Consulting/ Advisory Board*	*Funded Research*	*Royalties/ Patent*	*Stock Options*	*Ownership/ Equity Position*	*Employee*	*Other (please specify)*
AstraZeneca								Steering committee
Clovis Oncology								Steering committee
Tesaro								Steering committee

Off-Label Product Use

Will you be presenting or referencing off-label or investigational use of a therapeutic product?	
	No
X	Yes, please specify: • Rucaparib is approved in the United States for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy • Rucaparib is **not** approved for maintenance treatment anywhere else in the world

BACKGROUND

- ARIEL3 is a phase 3 study of the PARP inhibitor rucaparib 600 mg BID vs placebo following response to platinum-based chemotherapy for recurrent, platinum-sensitive ovarian cancer[1]
- Results of ARIEL3[1] supported the U.S. FDA approval of rucaparib for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy[2]
  - Rucaparib is not approved for maintenance treatment anywhere else in the world
  - An application to expand the EMA authorisation for rucaparib to include maintenance treatment has been submitted[3]
- This exploratory subgroup analysis investigates the effect of prior bevacizumab therapy on PFS in ARIEL3

BID, twice daily; EMA, European Medicines Agency; FDA, Food and Drug Administration; PARP, poly(ADP-ribose) polymerase; PFS, progression-free survival.

1. Coleman et al. *Lancet.* 2017;390:1949-61; 2. Rubraca (rucaparib) tablets [prescribing information]. Boulder, CO: Clovis Oncology, Inc.; 2018; 3. http://ir.clovisoncology.com/news-releases/news-release-details/clovis-oncology-submits-application-ema-expand-use-rubracarv-0. Accessed: 27 July 2018.

ARIEL3: STUDY DESIGN

Patient eligibility

- High-grade serous or endometrioid epithelial ovarian, fallopian tube, or primary peritoneal cancer
- Sensitive to penultimate platinum
- Responding to most recent platinum (CR or PR)*
- Prior bevacizumab was allowed, with the exception of bevacizumab maintenance after the most recent platinum
  - Prior bevacizumab use was not a stratification factor
- CA-125 within normal range
- No restriction on size of residual tumour
- ECOG PS ≤1
- No prior PARP inhibitors

Randomisation 2:1

Stratification

- HRR status by NGS mutation analysis
  - *BRCA1* or *BRCA2*
  - Non-*BRCA* HRR gene†
  - None of the above
- Response to recent platinum
  - CR
  - PR
- Progression-free interval after penultimate platinum
  - 6 to ≤12 months
  - >12 months

Rucaparib 600 mg BID n=375

Placebo BID n=189

- **Primary endpoint:** Investigator-assessed PFS (per RECIST)
- **Secondary endpoint:** BICR-assessed PFS (per RECIST)

*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 of last dose of chemotherapy). †*ATM, ATR, ATRX, BARD1, BLM, BRIP1, CHEK1, CHEK2, FANCA, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCI, FANCL, FANCM, MRE11A, NBN, PALB2, RAD50, RAD51, RAD51B, RAD51C, RAD51D, RAD52, RAD54L, RPA1*.

BICR, blinded independent central review; BID, twice daily; CA-125, cancer antigen 125; CR, complete response; ECOG PS, Eastern Cooperative Oncology Group Performance Status; GCIG, Gynecologic Cancer InterGroup; HRR, homologous recombination repair; NGS, next-generation sequencing; PARP, poly(ADP-ribose) polymerase; PFS, progression-free survival; PR, partial response; RECIST, Response Evaluation Criteria In Solid Tumors version 1.1.

ARIEL3: EXPLORATORY SUBGROUP ANALYSIS

- In the overall population, 83 (22.1%) patients in the rucaparib arm (n=375) and 43 (22.8%) patients in the placebo arm (n=189) had prior bevacizumab exposure

	Overall (n=564)	Rucaparib (n=375)	Placebo (n=189)
	n (%)		
Prior bevacizumab exposure	126 (22.3)	83 (22.1)	43 (22.8)
In first line*	71 (12.6)	50 (13.3)	21 (11.1)
In second line or later*	60 (10.6)	37 (9.9)	23 (12.2)
With chemotherapy in last treatment before ARIEL3†	23 (4.1)	14 (3.7)	9 (4.8)

Visit cutoff dates: efficacy analyses, 15 April 2017; safety analyses, 15 August 2017.
*Includes patients who received bevacizumab in first line and in second line or later (overall, 5 [0.1%]; rucaparib arm, 4 [0.1%]; placebo arm, 1 [0.1%]). †Bevacizumab maintenance therapy after the last treatment was not permitted.

BASELINE DEMOGRAPHICS

	Prior bevacizumab		No prior bevacizumab	
Characteristic	**Rucaparib (n=83)**	**Placebo (n=43)**	**Rucaparib (n=292)**	**Placebo (n=146)**
Age				
Median (range), years	60.0 (39.0–79.0)	62.0 (41.0–84.0)	61.0 (41.0–84.0)	62.0 (36.0–85.0)
Diagnosis, n (%)				
Epithelial ovarian cancer	66 (79.5)	36 (83.7)	246 (84.2)	123 (84.2)*
Fallopian tube cancer	9 (10.8)	2 (4.7)	23 (7.9)	8 (5.5)
Primary peritoneal cancer	8 (9.6)	5 (11.6)	23 (7.9)	14 (9.6)
Histology, n (%)				
Serous	80 (96.4)	41 (95.3)	277 (94.9)	138 (94.5)
Endometrioid	3 (3.6)	1 (2.3)	13 (4.5)	6 (4.1)
Mixed	0	1 (2.3)	1 (0.3)	2 (1.4)
Transitional	0	0	1 (0.3)	0
***BRCA* and LOH status, n (%)**				
BRCA mutant	28 (33.7)	11 (25.6)	102 (34.9)	55 (37.7)
BRCA wild type	55 (66.3)	32 (74.4)	190 (65.1)	91 (62.3)
LOH high	24 (28.9)	15 (34.9)	82 (28.1)	37 (25.3)
LOH low	28 (33.7)	12 (27.9)	79 (27.1)	42 (28.8)
LOH indeterminate†	3 (3.6)	5 (11.6)	29 (9.9)	12 (8.2)

Visit cutoff date: 15 April 2017. *One (0.7%) patient had a diagnosis of high-grade serous adenocarcinoma that was fallopian and/or ovarian in origin. †Tumour sample was not evaluable for percent of genomic LOH due to low tumour content or low aneuploidy.
LOH, loss of heterozygosity.

BASELINE DEMOGRAPHICS (CONTINUED)

	Prior bevacizumab		No prior bevacizumab	
Characteristic	**Rucaparib (n=83)**	**Placebo (n=43)**	**Rucaparib (n=292)**	**Placebo (n=146)**
ECOG PS				
0, n (%)	66 (79.5)	35 (81.4)	214 (73.3)	101 (69.2)
Number of prior chemotherapy regimens				
Median (range)	2 (2–5)	2 (2–5)	2 (2–6)	2 (2–6)
Number of platinum-based regimens				
Median (range)	2 (2–5)	2 (2–5)	2 (2–6)	2 (2–4)
2, n (%)	54 (65.1)	23 (53.5)	182 (62.3)	103 (70.5)
≥3, n (%)	29 (34.9)	20 (46.5)	110 (37.7)	43 (29.5)
Time to progression with penultimate platinum				
Median (range), months	15.6 (6.4–63.3)	14.6 (6.4–71.6)	13.3 (5.8–120.0)	14.8 (6.0–238.5)
6 to ≤12 months, n (%)	31 (37.3)	19 (44.2)	120 (41.1)	57 (39.0)
>12 months, n (%)	52 (62.7)	24 (55.8)	172 (58.9)	89 (61.0)
Response to last platinum				
CR per RECIST, n (%)	30 (36.1)	11 (25.6)	96 (32.9)	53 (36.3)
PR per RECIST or serologic response per GCIG CA-125 criteria, n (%)	53 (63.9)	32 (74.4)	196 (67.1)	93 (63.7)
Measurable disease at baseline (per investigator)				
Yes, n (%)	29 (34.9)	16 (37.2)	112 (38.4)	50 (34.2)
Bulky disease (any lesion >2 cm) at baseline (per independent radiological review)				
Yes, n (%)	14 (16.9)	8 (18.6)	57 (19.5)	21 (14.4)

Visit cutoff date: 15 April 2017.

CA-125, cancer antigen 125; CR, complete response; ECOG PS, Eastern Cooperative Oncology Group Performance Status; GCIG, Gynecologic Cancer InterGroup; PR, partial response; RECIST, Response Evaluation Criteria In Solid Tumors version 1.1.

ARIEL3: EXPLORATORY SUBGROUP ANALYSIS

- PFS was explored in 3 molecularly defined cohorts for the prior bevacizumab and no prior bevacizumab subgroups

Molecularly defined nested cohorts

Prior bevacizumab	No prior bevacizumab
***BRCA*-mutant cohort (n=39)** 28 rucaparib 11 placebo	***BRCA*-mutant cohort (n=157)** 102 rucaparib 55 placebo

Visit cutoff dates: efficacy analyses, 15 April 2017; safety analyses, 15 August 2017.
ITT, intent to treat; LOH, loss of heterozygosity; PFS, progression-free survival.

ARIEL3: EXPLORATORY SUBGROUP ANALYSIS

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Molecularly defined nested cohorts

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***BRCA*-mutant cohort (n=39)** 28 rucaparib 11 placebo	***BRCA*-mutant cohort (n=157)** 102 rucaparib 55 placebo
***BRCA*-mutant plus *BRCA* wild-type/high LOH cohort (n=78)** 52 rucaparib 26 placebo	***BRCA*-mutant plus *BRCA* wild-type/high LOH cohort (n=276)** 184 rucaparib 92 placebo

Visit cutoff dates: efficacy analyses, 15 April 2017; safety analyses, 15 August 2017.
ITT, intent to treat; LOH, loss of heterozygosity; PFS, progression-free survival.

ARIEL3: EXPLORATORY SUBGROUP ANALYSIS

- PFS was explored in 3 molecularly defined cohorts for the prior bevacizumab and no prior bevacizumab subgroups

Molecularly defined nested cohorts

Prior bevacizumab		No prior bevacizumab	
***BRCA*-mutant cohort (n=39)**		***BRCA*-mutant cohort (n=157)**	
28 rucaparib	11 placebo	102 rucaparib	55 placebo
***BRCA*-mutant plus *BRCA* wild-type/high LOH cohort (n=78)**		***BRCA*-mutant plus *BRCA* wild-type/high LOH cohort (n=276)**	
52 rucaparib	26 placebo	184 rucaparib	92 placebo
ITT population (n=126)		**ITT population (n=438)**	
83 rucaparib	43 placebo	292 rucaparib	146 placebo

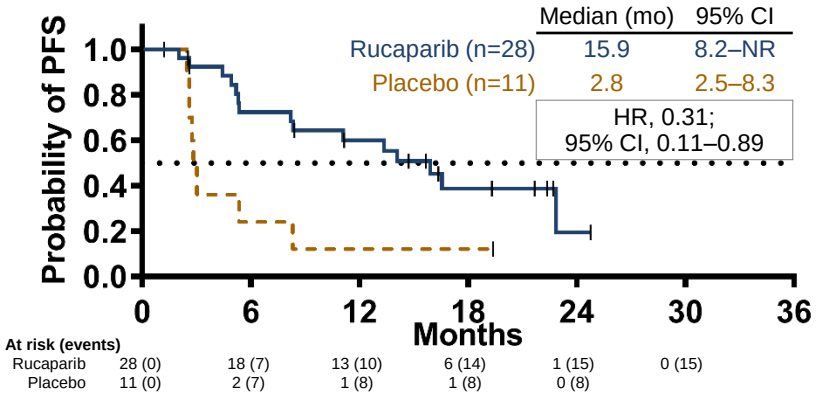
- Safety was assessed for all treated patients in the prior bevacizumab and no prior bevacizumab subgroups

Visit cutoff dates: efficacy analyses, 15 April 2017; safety analyses, 15 August 2017.
ITT, intent to treat; LOH, loss of heterozygosity; PFS, progression-free survival.

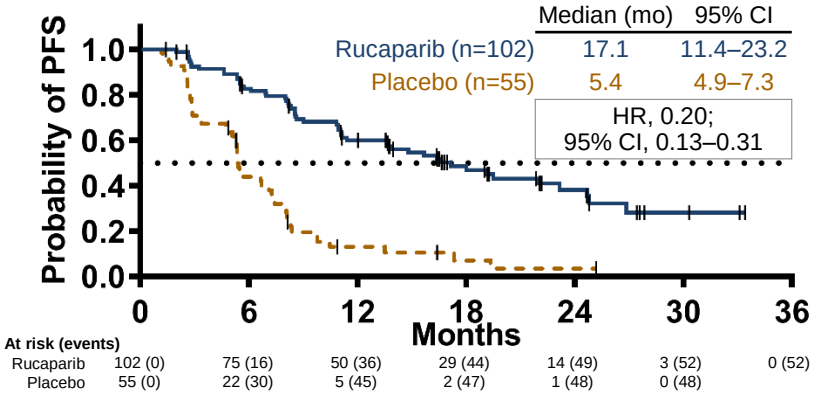
INVESTIGATOR-ASSESSED PFS

BRCA mutant

Prior bevacizumab



No prior bevacizumab

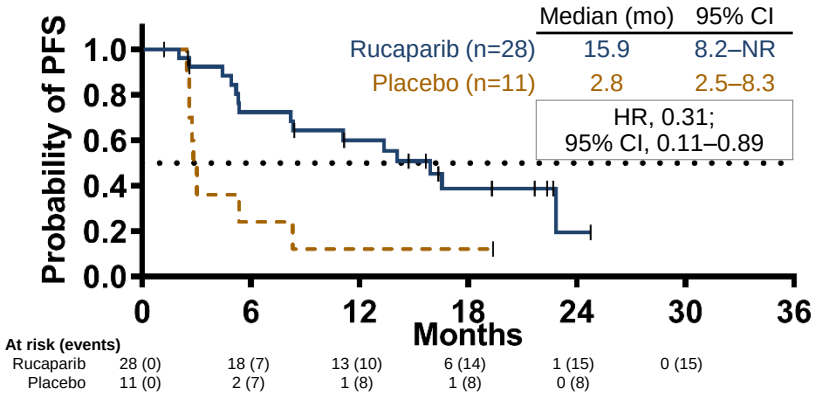


Visit cutoff date: 15 April 2017. HRs were estimated using the Cox proportional hazards model; *P* values for treatment-by-prior bevacizumab subgroup interaction were nonsignificant for all analyses.
CI, confidence interval; HR, hazard ratio; ITT, intent to treat; LOH, loss of heterozygosity; NR, not reached; PFS, progression-free survival.

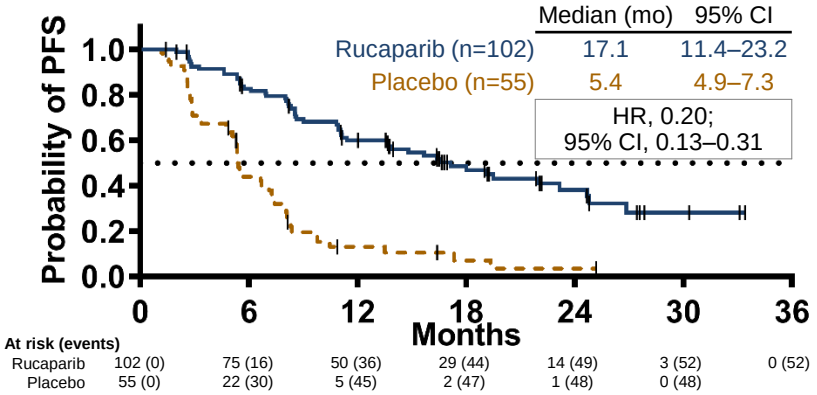
INVESTIGATOR-ASSESSED PFS

BRCA mutant

Prior bevacizumab

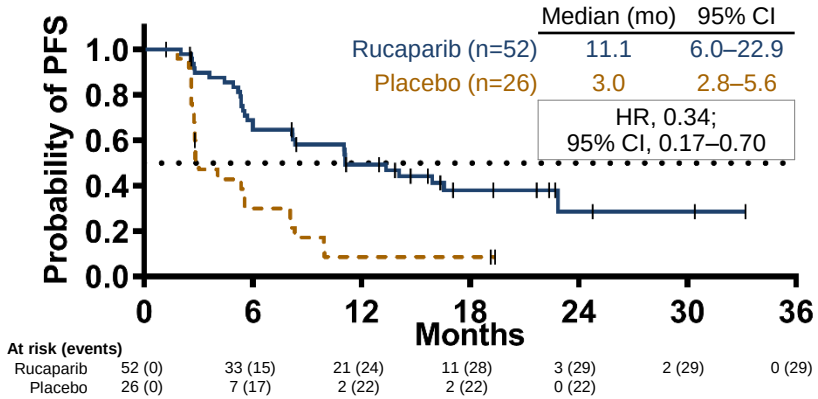


No prior bevacizumab

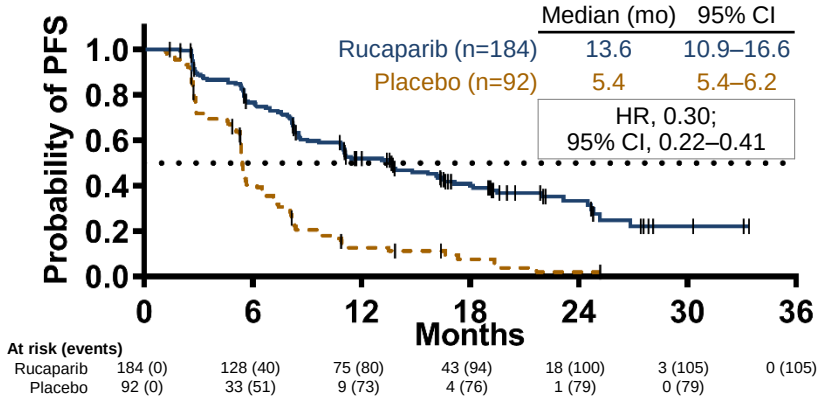


BRCA mutant + *BRCA* wild type/high LOH

Prior bevacizumab



No prior bevacizumab



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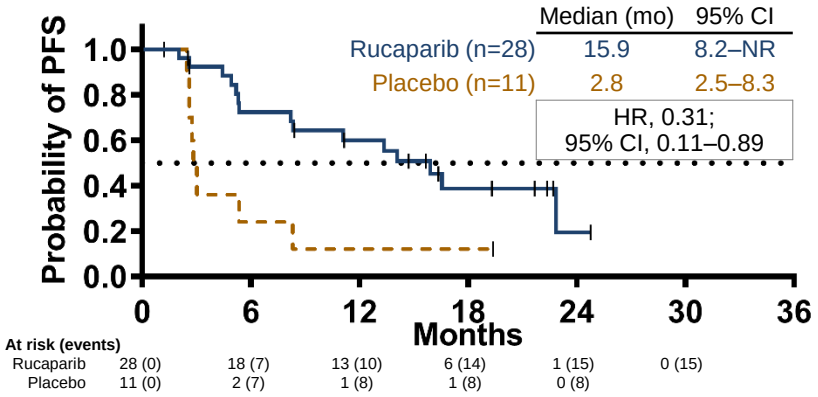
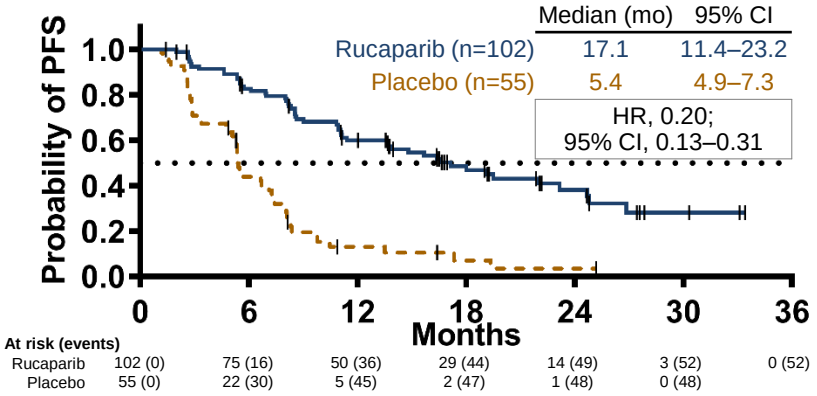
INVESTIGATOR-ASSESSED PFS

BRCA mutant

Prior bevacizumab

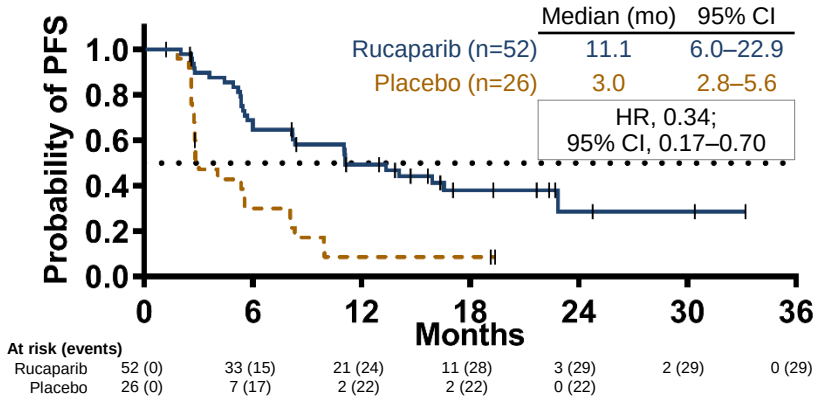


No prior bevacizumab

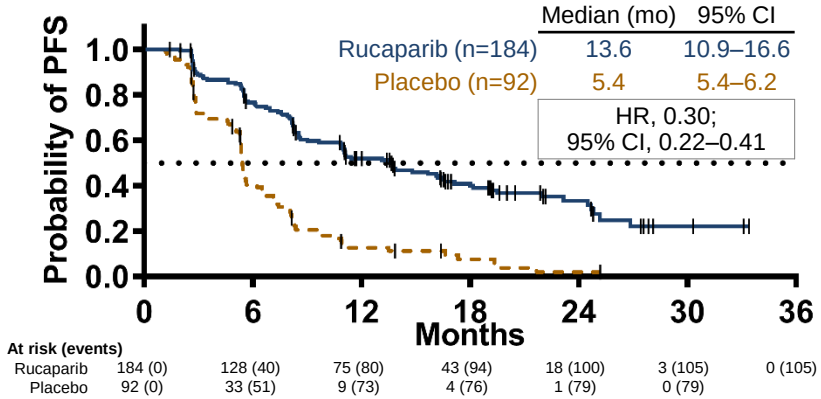


BRCA mutant + *BRCA* wild type/high LOH

Prior bevacizumab

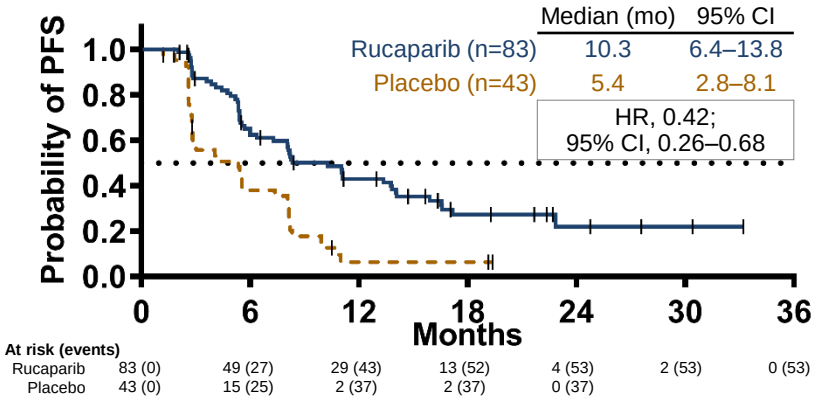


No prior bevacizumab

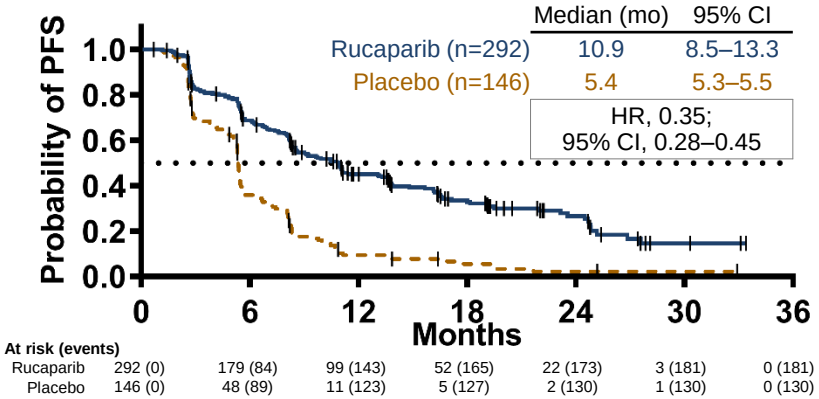


ITT population

Prior bevacizumab



No prior bevacizumab



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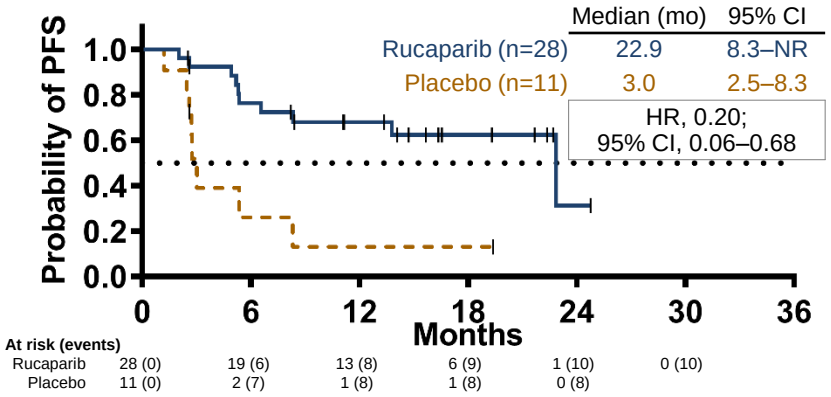
CI, confidence interval; HR, hazard ratio; ITT, intent to treat; LOH, loss of heterozygosity; NR, not reached; PFS, progression-free survival.

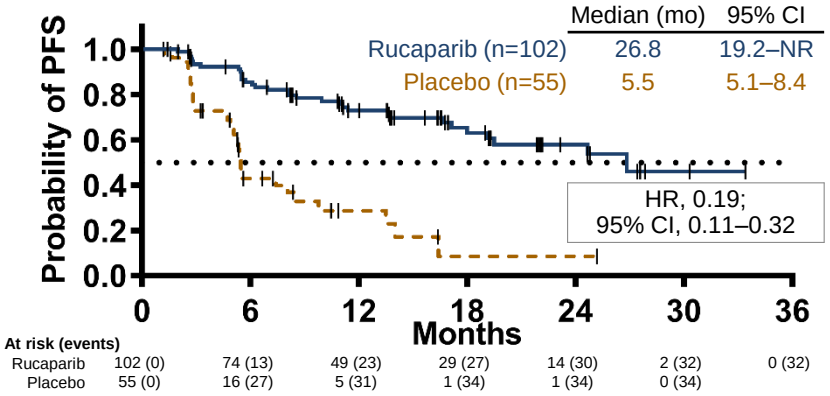
BICR-ASSESSED PFS

BRCA mutant

Prior bevacizumab

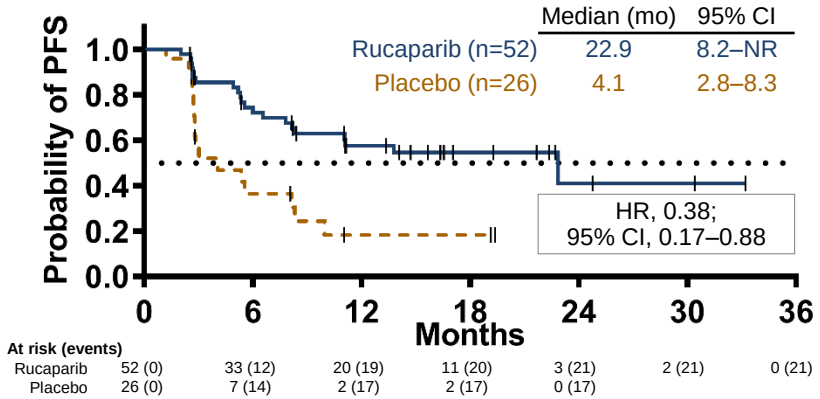


No prior bevacizumab

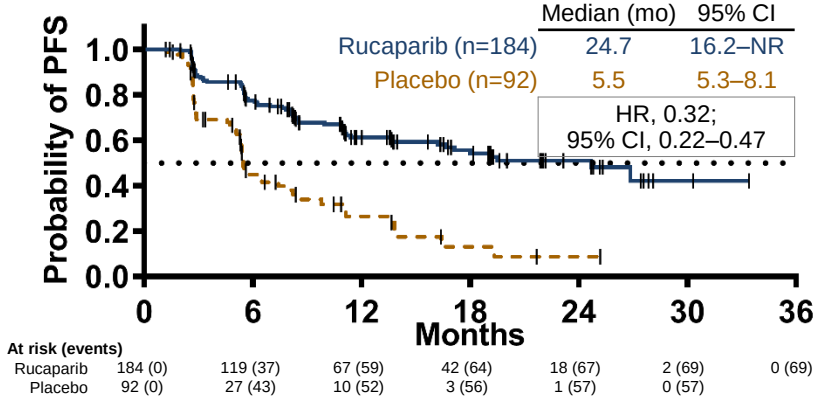


BRCA mutant + *BRCA* wild type/high LOH

Prior bevacizumab

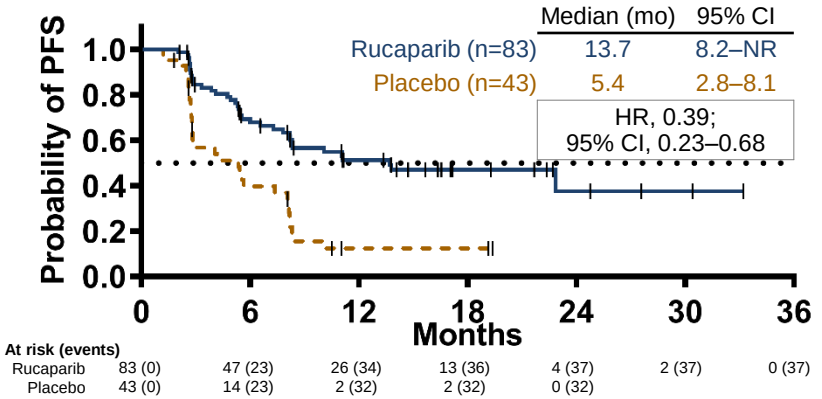


No prior bevacizumab

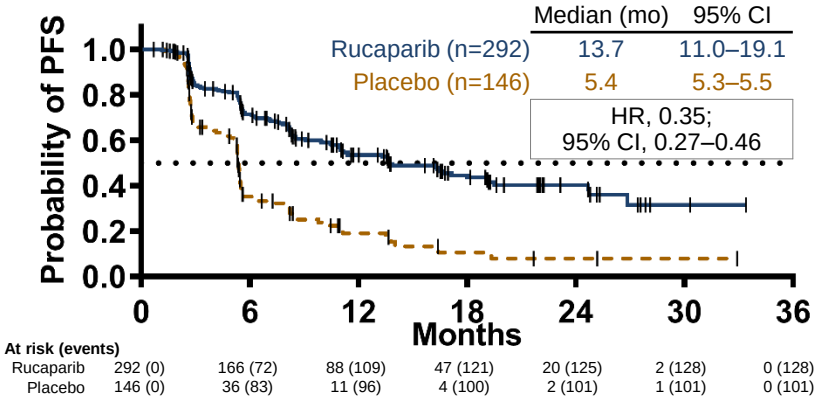


ITT population

Prior bevacizumab



No prior bevacizumab



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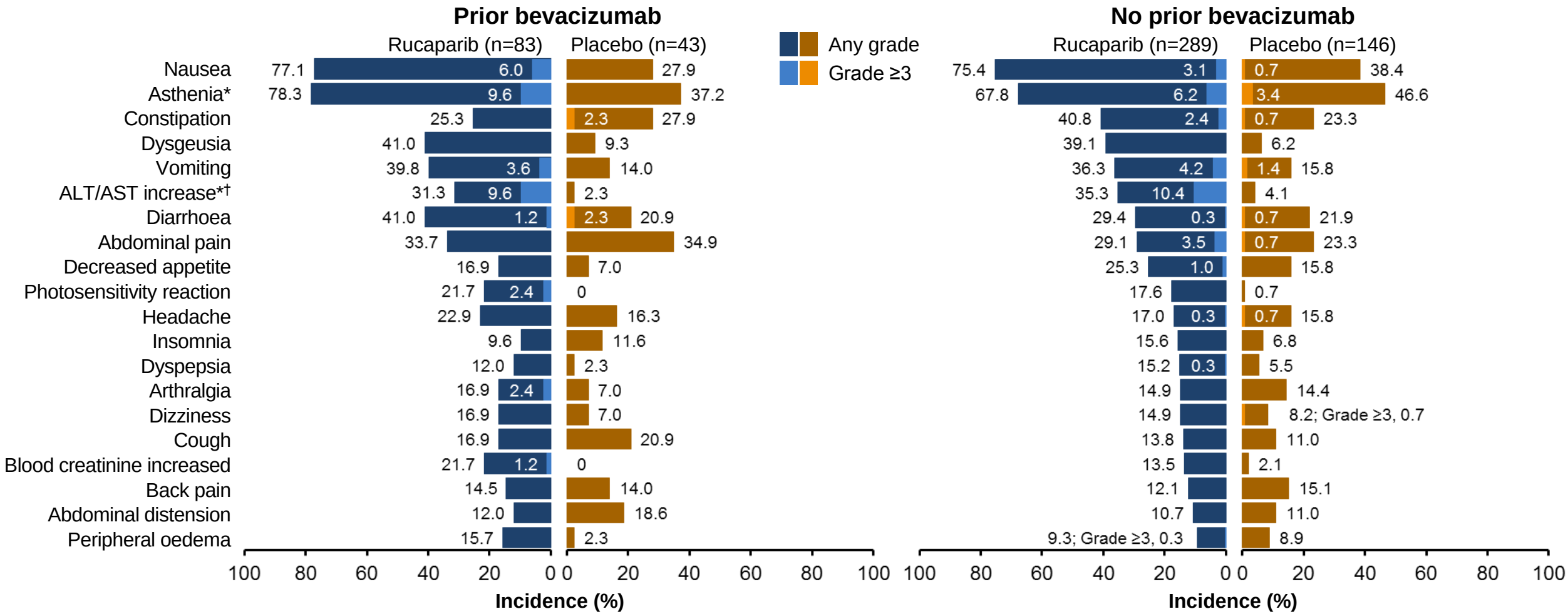
BICR, blinded independent central review; CI, confidence interval; HR, hazard ratio; ITT, intent to treat; LOH, loss of heterozygosity; NR, not reached; PFS, progression-free survival.

SUMMARY OF SAFETY

	Prior bevacizumab, n (%)		No prior bevacizumab, n (%)	
	Rucaparib (n=83)	**Placebo (n=43)**	**Rucaparib (n=289)***	**Placebo (n=146)**
Treatment interruption and/or dose reduction due to TEAE	69 (83.1)	2 (4.7)	196 (67.8)	18 (12.3)
Treatment interruption due to TEAE	63 (75.9)	2 (4.7)	175 (60.6)	17 (11.6)
Dose reduction due to TEAE	52 (62.7)	0	152 (52.6)	8 (5.5)
Discontinued due to TEAE†	10 (12.0)	0	45 (15.6)	3 (2.1)
Deaths due to TEAE	3 (3.6)	0	4 (1.4)	2 (1.4)
Deaths due to disease progression	1 (1.2)	0	1 (0.3)	1 (0.7)

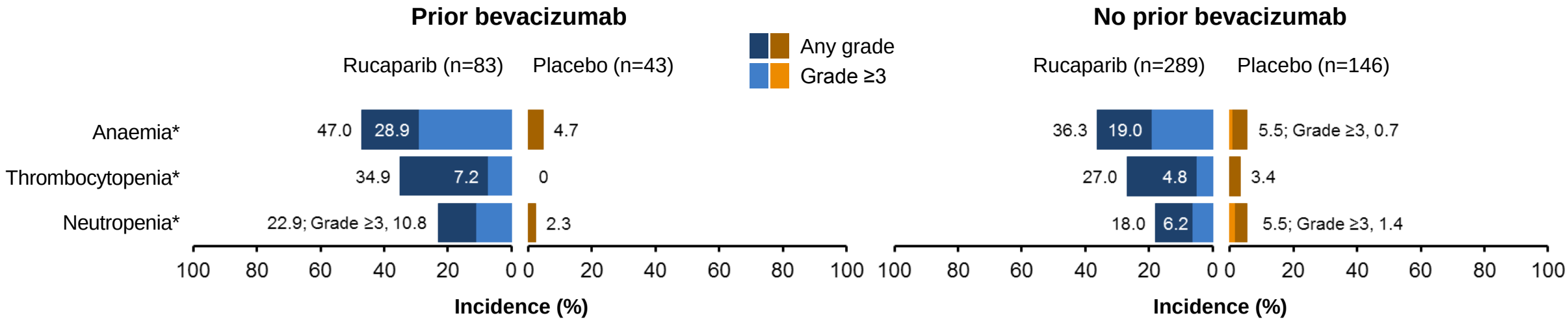
Visit cutoff date: 15 August 2017. *Three patients randomised to the rucaparib arm did not receive a dose of rucaparib and are excluded from the safety population. †Excluding disease progression.
TEAE, treatment-emergent adverse event.

MOST COMMON (≥15%) NONHAEMATOLOGIC TEAEs OF ANY GRADE IN PATIENTS IN EITHER SUBGROUP



Visit cutoff date: 15 August 2017. TEAEs sorted by decreasing incidence in rucaparib-treated patients with no prior bevacizumab.
*Combined terms. †Elevations were generally transient, self-limiting, and not associated with abnormal increases in bilirubin or other criteria for drug-induced hepatotoxicity.
ALT, alanine aminotransferase; AST, aspartate aminotransferase; TEAE, treatment-emergent adverse event.

MOST COMMON (≥15%) HAEMATOLOGIC TEAEs OF ANY GRADE IN PATIENTS IN EITHER SUBGROUP AND OTHER TEAEs OF INTEREST



- Hypertension (any grade) did not occur at a higher rate in patients with prior bevacizumab exposure (4.8% and 9.3% in the rucaparib and placebo arms, respectively) than in those without prior bevacizumab exposure (10.7% and 8.2% in the rucaparib and placebo arms, respectively)
- No TEAEs pertaining to gastrointestinal perforations and fistulae or complications of surgery and wound healing were reported in ≥2 patients in any subgroup

Visit cutoff date: 15 August 2017. TEAEs sorted by decreasing incidence in rucaparib-treated patients with no prior bevacizumab.
*Combined terms.
TEAE, treatment-emergent adverse event.

CONCLUSIONS

- Rucaparib maintenance treatment significantly improved PFS vs placebo in all 3 molecularly defined cohorts, regardless of prior bevacizumab use
  - Across cohorts, prior bevacizumab use did not significantly affect the magnitude of PFS improvement seen with rucaparib
- The safety profile was similar between rucaparib-treated patients in both subgroups and was consistent with that of the safety population reported previously[1]
  - Adverse events associated with bevacizumab use (eg, gastrointestinal perforations and fistulae, surgery and wound healing complications, and haemorrhage) were not commonly observed in either subgroup

ITT, intent to treat; PFS, progression-free survival.

1. Coleman et al. *Lancet*. 2017;390:1949-61.

ACKNOWLEDGEMENTS

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ARIEL3 co-coordinating investigators:

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- Jonathan A. Ledermann, UCL Cancer Institute and UCL Hospitals, London, UK

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