ASCO® Genitourinary Cancers Symposium

Rucaparib for metastatic castration-resistant prostate cancer (mCRPC): TRITON3 interim overall survival and efficacy of rucaparib vs docetaxel or second-generation androgen pathway inhibitor therapy

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Background and Rationale

- The PARP inhibitor rucaparib received accelerated approval in the US for the treatment of BRCA-altered mCRPC in patients previously treated with second-generation ARPI and taxane-based chemotherapy[1,2]
- TRITON3 compares rucaparib against physician's choice of either docetaxel or second-generation ARPI in patients with mCRPC and a BRCA or *ATM* alteration
- Here we present:
  - Primary endpoint of rPFS
  - Interim OS
  - Analyses of rucaparib compared individually with physician's choice of either docetaxel or second-generation ARPI

1. Abida et al. J Clin Oncol. 2020;38:3763-72. 2. Rubraca® (rucaparib) tablets [prescribing information]. Boulder, CO: Clovis Oncology, Inc.; 2022.
ARPI, androgen receptor pathway inhibitor; BRCA, *BRCA1* and *BRCA2*; mCRPC, metastatic castration-resistant prostate cancer; OS, overall survival; PARP, poly(ADP-ribose) polymerase; rPFS, radiographic progression-free survival; US, United States.

TRITON3 Study Design

Key eligibility criteria

- Chemotherapy-naïve mCRPC
- BRCA or *ATM* alteration[a]
- 1 prior second-generation ARPI in any setting[b]

Prior docetaxel or other taxane chemotherapy for castration-sensitive disease was permitted

Randomization 2:1

Stratification:

- ECOG PS 0 vs 1
- Hepatic metastases yes vs no
- *BRCA1* vs *BRCA2* vs *ATM*

Rucaparib (n=270)
600 mg BID

Physician's choice (n=135)[c]

Docetaxel (n=75)

or

Second-generation ARPI (n=60)

Abiraterone acetate or **Enzalutamide**

Patients who progress on physician's choice of treatment may be considered for crossover to rucaparib

Endpoints[d]

Primary:
- rPFS by IRR

Key secondary:
- OS
- ORR by IRR

Subgroup analyses:
- OS and rPFS for rucaparib vs docetaxel or second-generation ARPI

Visit cutoff date: 25 August 2022. [a]Determined by Foundation Medicine testing of tissue or plasma. [b]Protocol amendment 19 June 2018: patients' qualifying second-generation ARPI could be in any setting. [c]If chosen, patients received whichever second-generation ARPI had not yet been received. Docetaxel: 75 mg/m^2 Q21D, 10 cycles max; Abiraterone acetate: 1000 mg QD; Enzalutamide: 160 mg QD; [d]Tumor assessments were conducted at baseline and every 8 weeks for 24 weeks, then every 12 weeks, via CT/MRI and technetium-bone scans. [e]84 patients had IRR-confirmed progression, including 3 who were later re-evaluated as having non-progressive disease by IRR. ARPI, androgen receptor pathway inhibitor; BID, twice daily; BRCA, *BRCA1* and *BRCA2*; CT, computed tomography; ECOG PS, Eastern Cooperative Oncology Group performance status; IRR, independent radiology review; mCRPC, metastatic castration-resistant prostrate cancer; OS, overall survival; Q21D, every 21 days; QD, daily; rPFS, radiographic progression-free survival.

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Docetaxel (n=75)

or

Second-generation ARPI (n=60)

Abiraterone acetate or **Enzalutamide**

Crossover to rucaparib: 63/84[e] (75.0%)

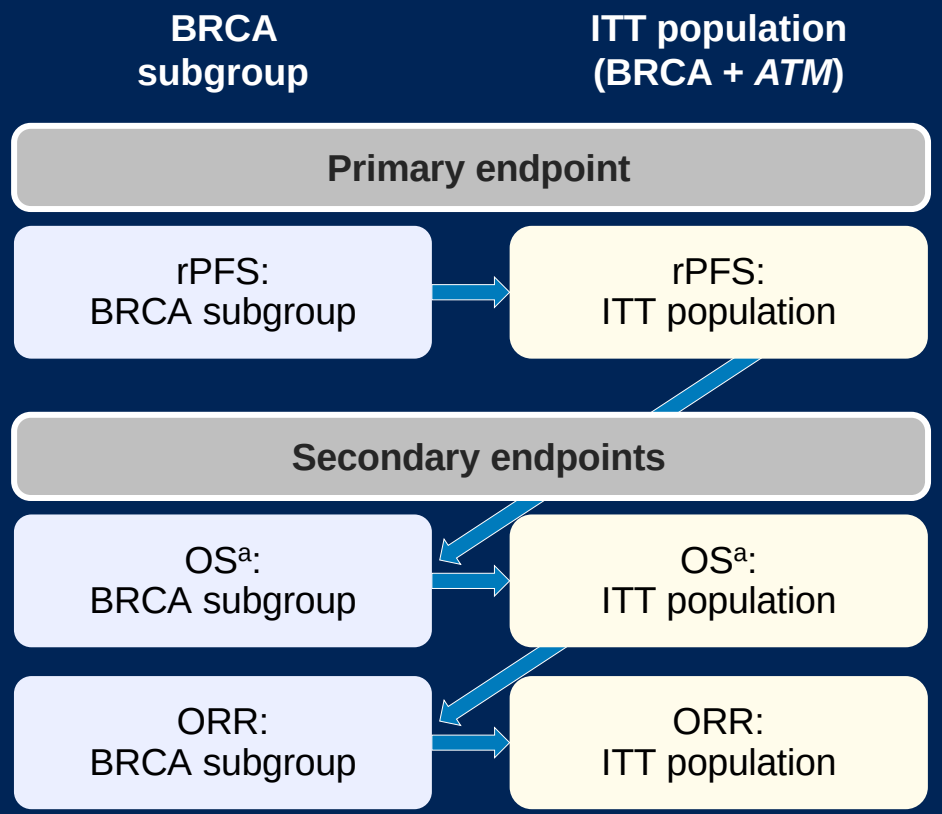
Randomized treatment:

- Docetaxel: 34/44 (77.3%)
- Second-generation ARPI: 29/40 (72.5%)

Patients who progress on physician's choice of treatment may be considered for crossover to rucaparib

Visit cutoff date: 25 August 2022. [a]Determined by Foundation Medicine testing of tissue or plasma. [b]Protocol amendment 19 June 2018: patients' qualifying second-generation ARPI could be in any setting. [c]If chosen, patients received whichever second-generation ARPI had not yet been received. Docetaxel: 75 mg/m^2 Q21D, 10 cycles max; Abiraterone acetate: 1000 mg QD; Enzalutamide: 160 mg QD; [d]Tumor assessments were conducted at baseline and every 8 weeks for 24 weeks, then every 12 weeks, via CT/MRI and technetium-bone scans. [e]84 patients had IRR-confirmed progression, including 3 who were later re-evaluated as having non-progressive disease by IRR. ARPI, androgen receptor pathway inhibitor; BID, twice daily; BRCA, *BRCA1* and *BRCA2*; CT, computed tomography; ECOG PS, Eastern Cooperative Oncology Group performance status; IRR, independent radiology review; mCRPC, metastatic castration-resistant prostrate cancer; OS, overall survival; Q21D, every 21 days; QD, daily; rPFS, radiographic progression-free survival.

TRITON3 Ordered Step-Down Analysis

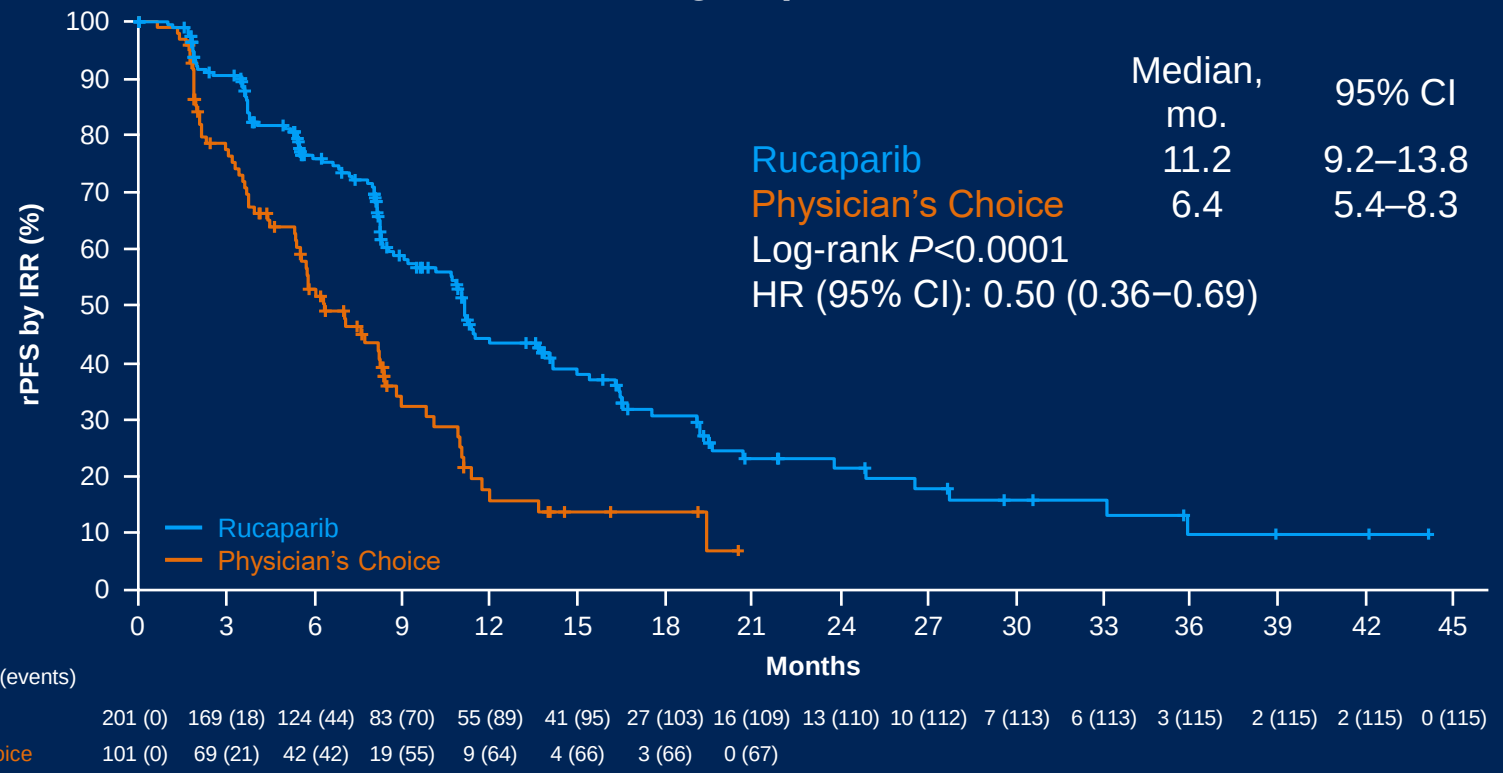


- The primary endpoint was first tested in the BRCA population and then, if statistically significant, in the ITT population
- Analysis for secondary endpoints continued in the same manner

[a]Following a protocol amendment on 18 February 2022, OS was elevated to be the first secondary endpoint in the step-down analysis procedure.
BRCA, *BRCA1* and *BRCA2*; ITT, intent to treat; ORR, objective response rate; OS, overall survival; rPFS, radiographic progression-free survival.

Radiographic PFS

BRCA subgroup[1]



	Median, mo.	95% CI
Rucaparib	11.2	9.2–13.8
Physician's Choice	6.4	5.4–8.3

Log-rank *P*<0.0001
HR (95% CI): 0.50 (0.36−0.69)

Patients at risk (events)

Rucaparib	201 (0)	169 (18)	124 (44)	83 (70)	55 (89)	41 (95)	27 (103)	16 (109)	13 (110)	10 (112)	7 (113)	6 (113)	3 (115)	2 (115)	2 (115)	0 (115)
Physician's Choice	101 (0)	69 (21)	42 (42)	19 (55)	9 (64)	4 (66)	3 (66)	0 (67)								

ITT population[1]

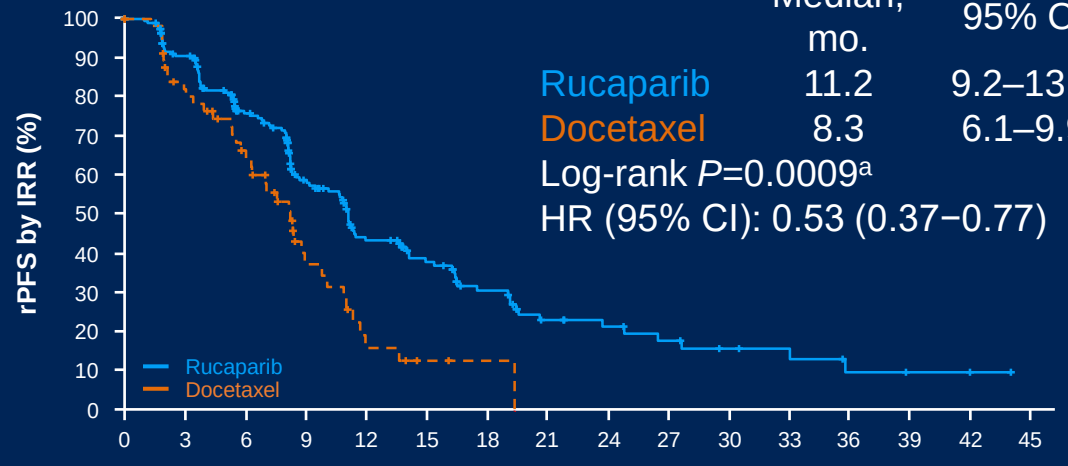
	Rucaparib (n=270)	Physician's Choice (n=135)
Median rPFS, mos (95% CI)	10.2 (8.3–11.2)	6.4 (5.6–8.2)
Log-rank *P*	0.0003	
HR (95% CI)	0.61 (0.47–0.80)	

Visit cutoff date: 25 August 2022. BRCA subgroup data maturity (rucaparib vs physician's choice): 182/302 (60.3%). 1. Bryce et al. Presented at the 2022 PCF Annual Retreat.
BRCA, *BRCA1* and *BRCA2*; HR, hazard ratio; IRR, independent radiology review; ITT, intent to treat; PFS, progression-free survival; rPFS, radiographic progression-free survival.

Radiographic PFS: Physician's Choice Subgroups

BRCA subgroup

Rucaparib vs Docetaxel



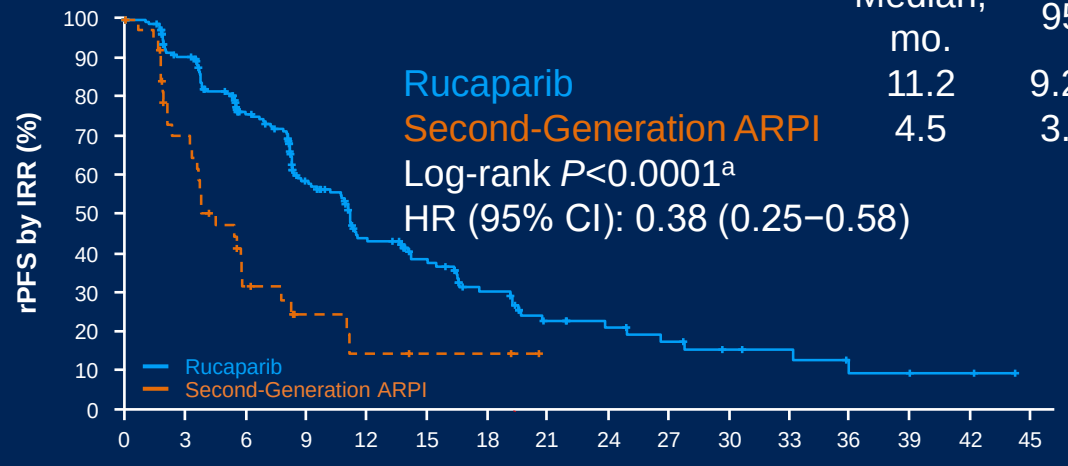
	Median, mo.	95% CI
Rucaparib	11.2	9.2–13.8
Docetaxel	8.3	6.1–9.9

Log-rank *P*=0.0009[a]
HR (95% CI): 0.53 (0.37−0.77)

Patients at risk (events)

Rucaparib	201 (0)	124 (44)	55 (89)	27 (103)	13 (110)	7 (113)	3 (115)	2 (115)
Docetaxel	60 (0)	32 (18)	6 (36)	1 (38)	0 (39)			

Rucaparib vs Second-Generation ARPI



	Median, mo.	95% CI
Rucaparib	11.2	9.2–13.8
Second-Generation ARPI	4.5	3.3–5.8

Log-rank *P*<0.0001[a]
HR (95% CI): 0.38 (0.25−0.58)

Patients at risk (events)

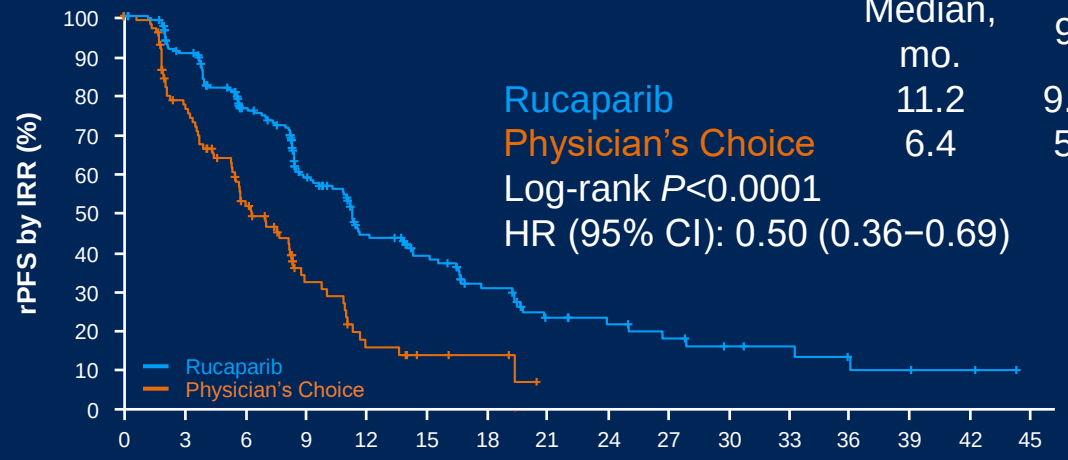
Rucaparib	201 (0)	124 (44)	55 (89)	27 (103)	13 (110)	7 (113)	3 (115)	2 (115)
Second-Generation ARPI	41 (0)	10 (24)	3 (28)	2 (28)	0 (28)			

ITT population	Rucaparib (n=270)	Docetaxel (n=75)	Second-Generation ARPI (n=60)
rPFS, mos (95% CI)	10.2 (8.3–11.2)	8.3 (6.1–10.1)	4.5 (3.7–5.8)
Log-rank *P*	–	0.0066[a]	<0.0001[a]
HR (95% CI)	–	0.64 (0.46–0.88)	0.47 (0.34–0.66)

[a]Nominal. Visit cutoff date: 25 August 2022.
ARPI, androgen receptor pathway inhibitor; BRCA, *BRCA1* and *BRCA2*; HR, hazard ratio; IRR, independent radiology review; ITT, intent to treat; PFS, progression-free survival; rPFS, radiographic progression-free survival.

Radiographic PFS: BRCA and *ATM* Subgroups

BRCA subgroup[1]



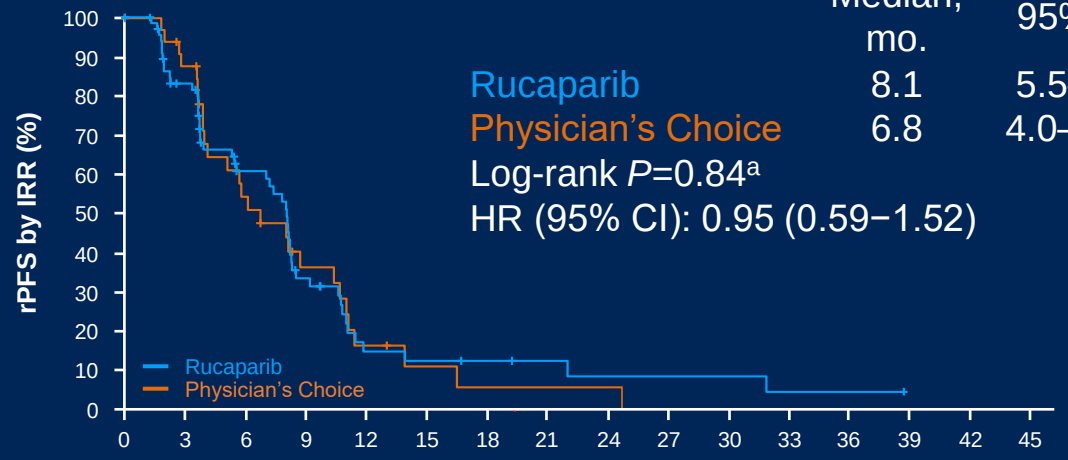
	Median, mo.	95% CI
Rucaparib	11.2	9.2–13.8
Physician's Choice	6.4	5.4–8.3

Log-rank *P*<0.0001
HR (95% CI): 0.50 (0.36−0.69)

Patients at risk (events)

Rucaparib	201 (0)	124 (44)	55 (89)	27 (103)	13 (110)	7 (113)	3 (115)	2 (115)
Physician's Choice	101 (0)	42 (42)	9 (64)	3 (66)	0 (67)			

ATM subgroup[1]



	Median, mo.	95% CI
Rucaparib	8.1	5.5–8.3
Physician's Choice	6.8	4.0–10.4

Log-rank *P*=0.84[a]
HR (95% CI): 0.95 (0.59−1.52)

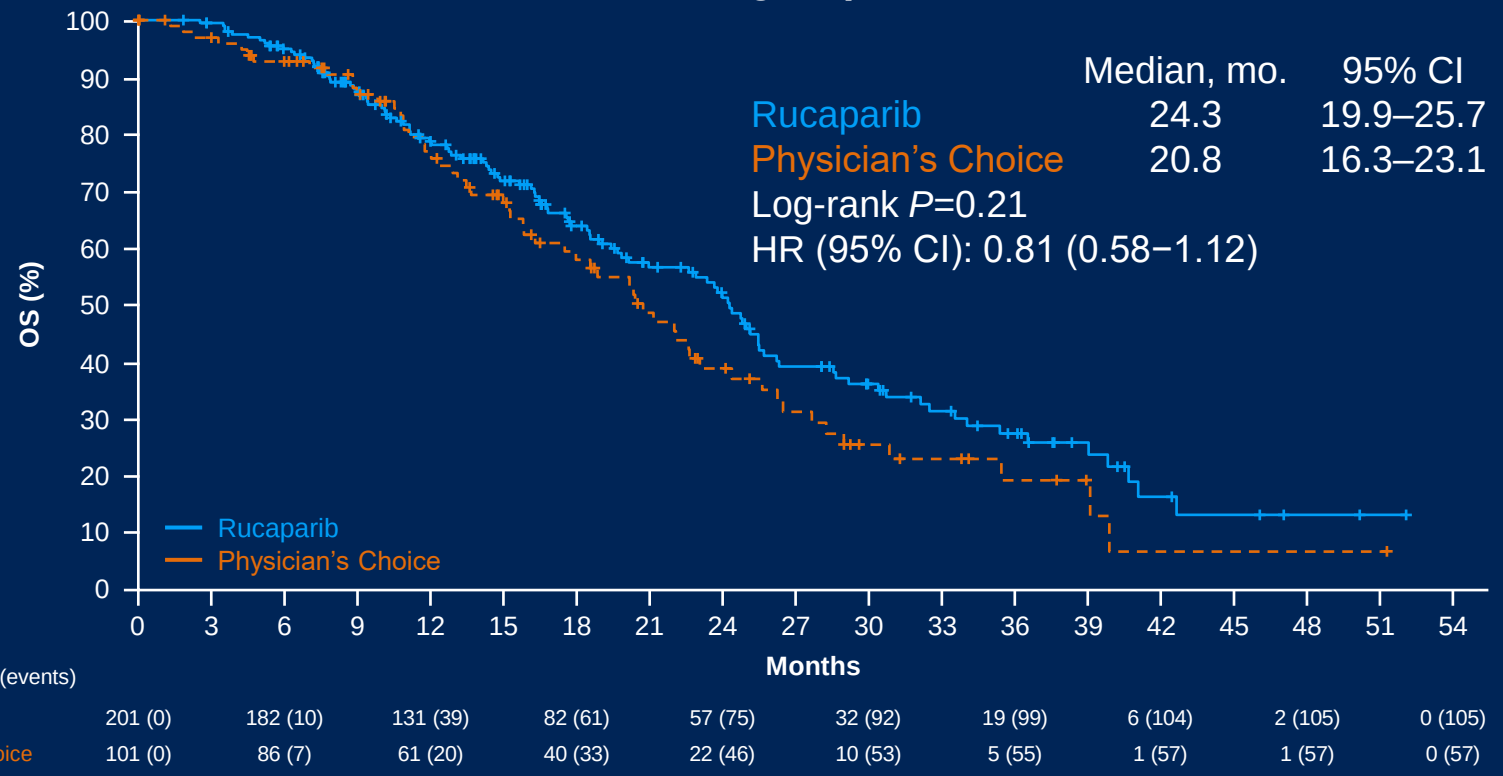
Patients at risk (events)

Rucaparib	69 (0)	31 (24)	6 (46)	4 (47)	2 (48)	2 (48)	1 (49)	0 (49)
Physician's Choice	34 (0)	16 (14)	4 (24)	1 (26)	1 (26)	0 (27)		

[a]Nominal. Visit cutoff date: 25 August 2022. 1. Bryce et al. Presented at the 2022 PCF Annual Retreat.
BRCA, *BRCA1* and *BRCA2*; HR, hazard ratio; IRR, independent radiology review; PFS, progression-free survival; rPFS, radiographic progression-free survival.

Interim OS

BRCA subgroup



ITT population

	Rucaparib (n=270)	Physician's Choice (n=135)
Median OS, mos (95% CI)	23.6 (19.7–25.0)	20.9 (17.5–24.4)
Log-rank *P*	0.67[a]	
HR (95% CI)	0.94 (0.72–1.23)	

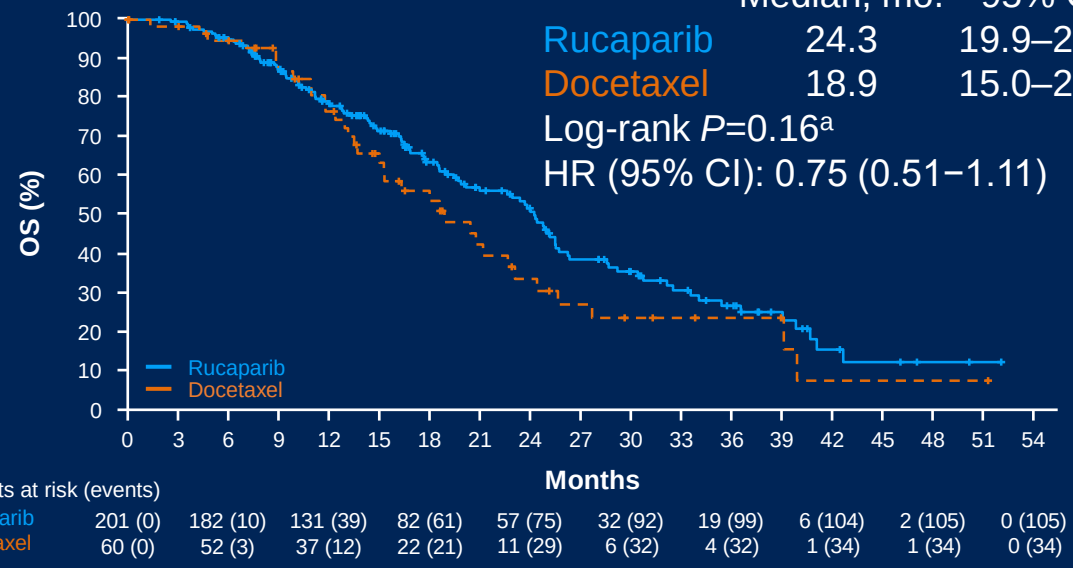
- BRCA subgroup data maturity (rucaparib vs physician's choice): 162/302 (53.6%)
- Target maturity for final analysis: 70%

[a]Nominal. Visit cutoff date: 25 August 2022. BRCA, *BRCA1* and *BRCA2*; HR, hazard ratio; ITT, intent to treat; OS, overall survival.

Interim OS: Physician's Choice Subgroups

BRCA subgroup

Rucaparib vs Docetaxel

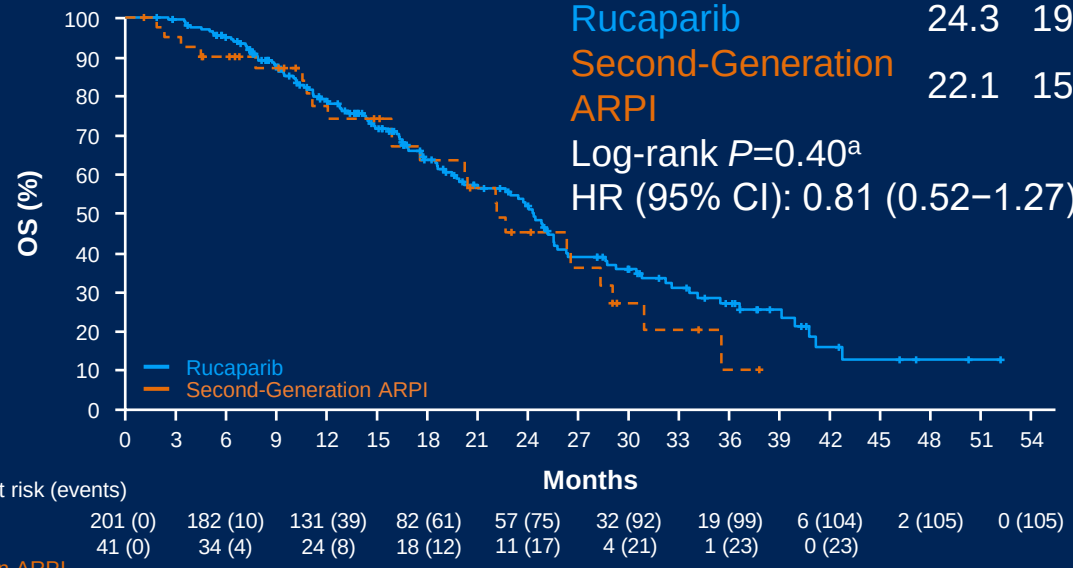


	Median, mo.	95% CI
Rucaparib	24.3	19.9–25.7
Docetaxel	18.9	15.0–23.1

Log-rank *P*=0.16[a]
HR (95% CI): 0.75 (0.51−1.11)

Patients at risk (events)										
Rucaparib	201 (0)	182 (10)	131 (39)	82 (61)	57 (75)	32 (92)	19 (99)	6 (104)	2 (105)	0 (105)
Docetaxel	60 (0)	52 (3)	37 (12)	22 (21)	11 (29)	6 (32)	4 (32)	1 (34)	1 (34)	0 (34)

Rucaparib vs Second-Generation ARPI



	Median, mo.	95% CI
Rucaparib	24.3	19.9–25.7
Second-Generation ARPI	22.1	15.9–28.3

Log-rank *P*=0.40[a]
HR (95% CI): 0.81 (0.52−1.27)

Patients at risk (events)										
Rucaparib	201 (0)	182 (10)	131 (39)	82 (61)	57 (75)	32 (92)	19 (99)	6 (104)	2 (105)	0 (105)
Second-Generation ARPI	41 (0)	34 (4)	24 (8)	18 (12)	11 (17)	4 (21)	1 (23)	0 (23)		

ITT population	Rucaparib (n=270)	Docetaxel (n=75)	Second-Generation ARPI (n=60)
Median OS, mos (95% CI)	23.6 (19.7–25.0)	19.1 (15.3–23.1)	22.1 (17.2–29.0)
Log-rank *P*	–	0.20[a]	0.90[a]
HR (95% CI)	–	0.80 (0.58–1.11)	1.01 (0.70–1.46)

[a]Nominal. Visit cutoff date: 25 August 2022. ARPI, androgen receptor pathway inhibitor; BRCA, *BRCA1* and *BRCA2*; HR, hazard ratio; ITT, intent to treat; OS, overall survival.

Baseline Characteristics in the ITT Population (1)

	Rucaparib (n=270)	Physician's Choice		
		Docetaxel (n=75)	Second-Generation ARPI (n=60)	Total (n=135)
Median age, years (range)	70 (45–90)	70 (47–88)	72 (54–92)	71 (47–92)
ECOG PS 0, n (%)	132 (49)	35 (47)	33 (55)	68 (50)
Alteration, (%)				
BRCA1	29 (11)	9 (12)	6 (10)	15 (11)
BRCA2	172 (64)	51 (68)	35 (58)	86 (64)
ATM	69 (26)	15 (20)	19 (32)	34 (25)
Baseline PSA, ng/mL, median (range)	27 (0.1–1247)	29 (0.2–1031)	29 (0–1039)	29 (0–1039)
Gleason score ≥8 at diagnosis, n (%)	173 (64)	59 (79)	37 (62)	96 (71)
Measurable disease per IRR, n (%)	106 (39)	34 (45)	21 (35)	55 (41)
Metastases per IRR, n (%)				
Bone	235 (87)	65 (87)	49 (82)	114 (84)
Bone-only	117 (43)	31 (41)	22 (37)	53 (39)
Nodal	118 (44)	36 (48)	24 (40)	60 (44)
Visceral	74 (27)	21 (28)	25 (42)	46 (34)

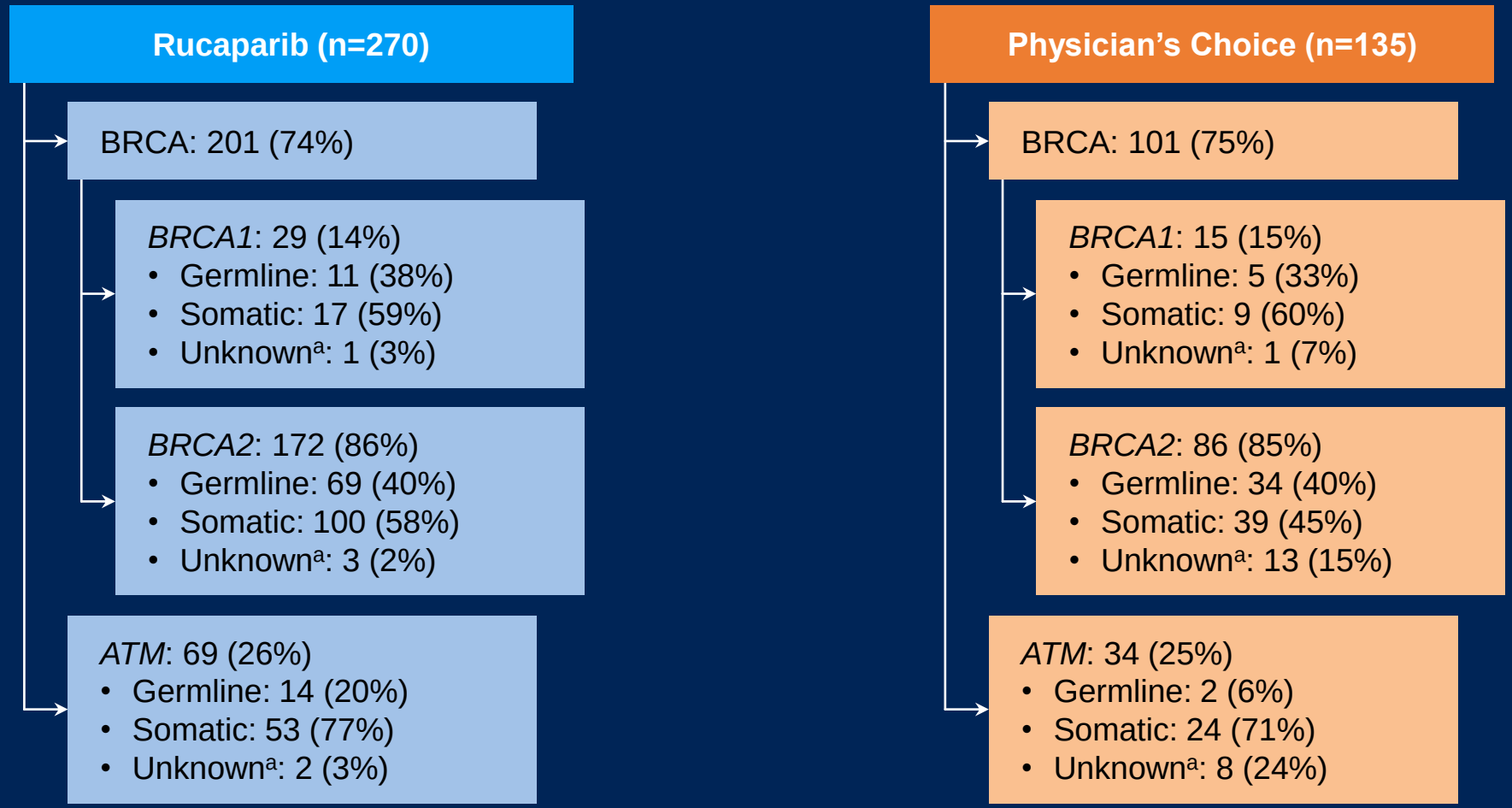
ARPI, androgen receptor pathway inhibitor; CRPC, castration-resistant prostate cancer; ECOG PS, Eastern Cooperative Oncology Group performance status; HSPC, hormone-sensitive prostate cancer; IRR, independent radiology review; ITT, intent to treat; PSA, prostate-specific antigen.

Baseline Characteristics in the ITT Population (2)

	Rucaparib (n=270)	Physician's Choice		
		Docetaxel (n=75)	Second-Generation ARPI (n=60)	Total (n=135)
Prior anticancer therapies, n (%)				
Second-generation ARPI[a]				
Abiraterone acetate	150 (56)	47 (63)	33 (55)	80 (59)
Apalutamide	8 (3)	0	1 (2)	1 (1)
Enzalutamide	119 (44)	33 (44)	28 (47)	61 (45)
Docetaxel for HSPC	63 (23)	12 (16)	16 (27)	28 (21)
No prior CRPC therapies, n (%)	48 (18)	18 (24)	8 (13)	26 (19)

ARPI, androgen receptor pathway inhibitor; CRPC, castration-resistant prostate cancer; ECOG PS, Eastern Cooperative Oncology Group performance status; HSPC, hormone-sensitive prostate cancer; IRR, independent radiology review; ITT, intent to treat; PSA, prostate-specific antigen.

BRCA and *ATM* Alterations in the ITT Population



[a]Sample not collected. BRCA, *BRCA1* and *BRCA2*; ITT, intent to treat.

Safety Summary

n (%)	Rucaparib (n=270)	Physician's Choice					
		Docetaxel (n=71)		Second-Generation ARPI (n=59)		Total (n=130)	
At least 1 any-grade TEAE	270 (100)	71 (100)		58 (98)		129 (99)	
At least 1 grade ≥3 TEAE	161 (60)	43 (61)		26 (44)		69 (53)	
Dose reductions due to TEAEs	104 (39)	21 (30)		11 (19)		32 (25)	
Dose interruptions due to TEAEs	142 (53)	19 (27)		12 (20)		31 (24)	
Discontinuations due to TEAEs	40 (15)	23 (32)		5 (8)		28 (22)	
Death due to TEAEs	5 (2)	0		3 (5)		3 (2)	
Most frequently reported TEAEs	**Any grade**	**Grade ≥3**	**Any grade**	**Grade ≥3**	**Any grade**	**Grade ≥3**	**Any grade**	**Grade ≥3**
Asthenia/fatigue	165 (61)	19 (7)	48 (68)	7 (10)	34 (58)	5 (8)	82 (63)	12 (9)
Nausea	134 (50)	7 (3)	11 (15)	1 (1)	14 (24)	0	25 (19)	1 (1)
Anemia/hemoglobin decreased	126 (47)	64 (24)	10 (14)	1 (1)	13 (22)	0	23 (18)	1 (1)
Neuropathy[a]	25 (9)	0	34 (48)	4 (6)	2 (3)	0	36 (28)	4 (3)

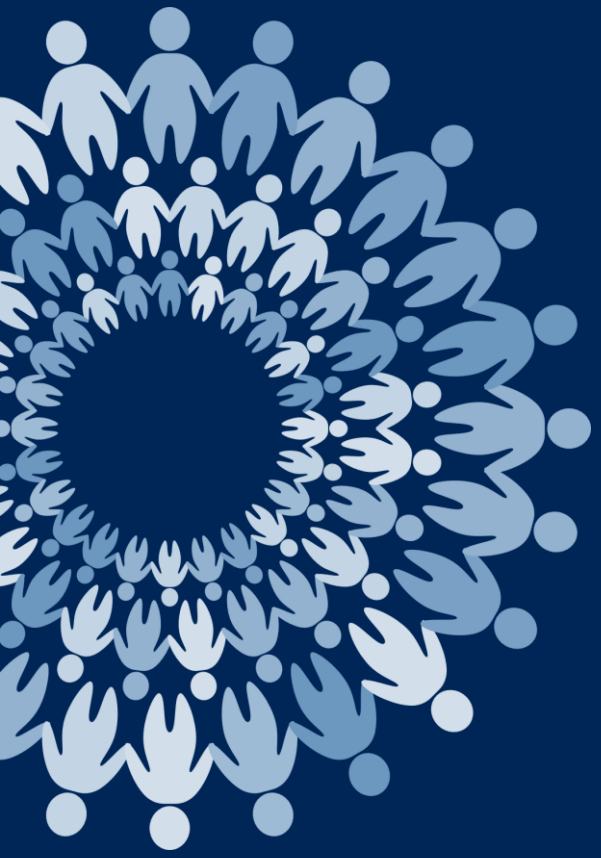
- At visit cutoff, 33 (12%) patients were ongoing on rucaparib vs 1 (1%) patient on docetaxel and 4 (7%) patients on second-generation ARPI
- 29% of rucaparib-arm patients received ≥1 blood transfusion vs 2% of those receiving physician's choice
- No reported cases of MDS and/or AML

Visit cutoff date: 25 August 2022. [a]Neuropathy includes neurotoxicity, paresthesia, peripheral motor neuropathy, peripheral neuropathy, peripheral sensory neuropathy, and polyneuropathy.
AML, acute myeloid leukemia; ARPI, androgen receptor pathway inhibitor; MDS, myelodysplastic syndrome; TEAE, treatment-emergent adverse event.

Conclusions

- TRITON3 met its primary endpoint of improving rPFS by the use of rucaparib vs physician's choice of therapy
  - Rucaparib reduced risk of imaging-based progression or death by half in patients with BRCA alterations
  - Rucaparib improved rPFS vs both docetaxel and second-generation ARPI therapy in the BRCA subgroup and ITT population
- Three quarters of patients in the physician's choice arm who had progressive disease crossed over to rucaparib upon progression
  - OS results are immature (54% in the BRCA subgroup)
- In all treatment groups, the most frequent TEAE was asthenia/fatigue
  - No cases of MDS and/or AML were reported

AML, acute myeloid leukemia; ARPI, androgen receptor pathway inhibitor; BRCA, *BRCA1* and *BRCA2*; ARPI, androgen receptor pathway inhibitor; ITT, intent to treat; MDS, myelodysplastic syndrome; OS, overall survival; rPFS, radiographic progression-free survival; TEAE, treatment-emergent adverse event.



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