NUCLEAR MEDICINE UPDATES

REVIEW OF THE 2024 ASCO & ESMO ANNUAL MEETINGS

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MARRIOTT IRVINE SPECTRUM - OCT 26, 2024

OBJECTIVES/OUTLINE

- Examine and review the newly FDA approved PET tracers with a focus on PSMA prostate imaging

- Review recent theranostic clinical trial results in the GU space
  - PSMAFORE
  - SPLASH
  - PEACE 3

DIAG*NOSTICS* + *THERA*PEUTICS = *THERANOSTICS*

A new generation of diagnostic PET agents has led to targeted therapy in oncology

‘Old’ tracers

- F-18 Fluorodeoxyglucose (FDG)
- F-18 Sodium Fluoride

‘New’ tracers

- Ga-68 DOTATATE
- Cu-64 DOTATATE
- Ga-68 PSMA
- F-18 DCFPyL (PyL) PSMA
- F-18 rhPSMA-7.3
- Cu-64 PSMA I&T (in trials)
- F-18 Fluoroestradiol (FES)
- Cu-64, F-18, & Ga-68 FAPI (in trials)
- Zr-89 Girentuximab (near FDA approval)

Theranostic agents

- Lu-177 DOTATATE
- Ac-225 DOTATATE (in trials)
- Lu-177 PSMA-617
- Lu-177 Ju591 rosopatamab (in trials)
- Ac-225 PSMA (in trials)

ASCO Genitourinary Cancers Symposium

PSMAfore: a phase 3 study to compare ^{177}Lu-PSMA-617 treatment with a change in androgen receptor pathway inhibitor in taxane-naive patients with mCRPC

A. Oliver Sartor[1], Michael J. Morris[2], Kim N. Chi[3], Johann S. de Bono[4], Neal Shore[5], Michael Crosby[6], Teri Kreisl[7], and Karim Fizazi[8]

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PRESENTED BY: A. Oliver Sartor, M.D.

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Background and Rationale

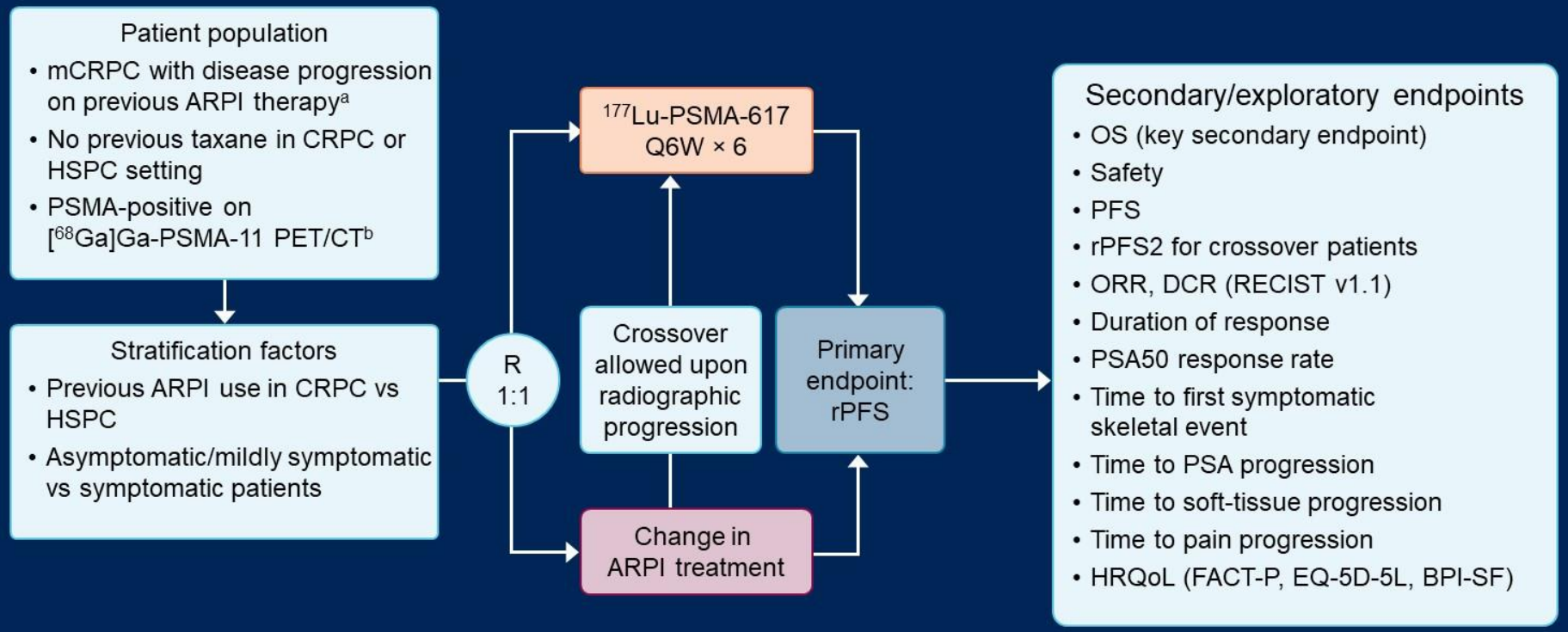
- mCRPC is a significant cause of morbidity and mortality despite the availability of treatment options[1,2]
- ARPIs and taxanes are approved for prolonging survival in patients with mCRPC[3]
  - ARPIs are increasingly being used at earlier disease stages and resistance to treatment can develop[4]
  - Cross-resistance between ARPIs may occur[5]; additionally, many patients are not eligible for chemotherapy owing to comorbidities or frailty, or the refusal of taxane-based chemotherapy because of its known side effects[6,7]
  - This leaves limited treatment options for mCRPC
- PSMA is a promising theranostic target in prostate cancer owing to its expression being highly upregulated in prostate cancer tissue, and its restricted expression in non–prostate-cancer tissue[8]; additionally, PSMA is highly expressed on the tumor cell membrane and functions as an internalizing cell surface receptor[9]
- [^{177}Lu]Lu-PSMA-617 (^{177}Lu-PSMA-617) is a high-affinity PSMA-targeted radioligand therapy that delivers β-particle radiation to PSMA-expressing cells and their surrounding microenvironment[10–12]
- In the phase 3 VISION trial, ^{177}Lu-PSMA-617 significantly prolonged rPFS and OS in patients with mCRPC who had previously been treated with ≥1 ARPI and 1 or 2 taxanes[13]

The aim of the PSMAfore study (NCT04689828) is to determine whether ^{177}Lu-PSMA-617 improves rPFS compared with a change in ARPI in patients with mCRPC who have been previously treated with an alternative ARPI, but have not been exposed to taxanes in mCRPC or mHSPC settings

ARPI, androgen receptor pathway inhibitor; mCRPC, metastatic castration-resistant prostate cancer; mHSPC, metatstatic hormone-sensitive prostate cancer; PSMA, prostate-specific membrane antigen; OS, overall survival; rPFS, radiographic progression-free survival.

1. Sartor O, et al. *N Engl J Med.* 2018;378:645–657. 2. Nuhn P, et al. *Eur Urol.* 2019;75:88–99. 3. Sartor O, et al. *Am Soc Clin Oncol Educ Book.* 2012; doi: 10.14694/EdBook_AM.2012.32.174. 4. Shore N, et al. *Urology.* 2017;109:6–18. 5. van Soest RJ, et al. *Eur Urol.* 2015;67:981–985. 6. Lissbrant IF, et al. *Acta Oncol.* 2013;52:1593–1601. 7. Schutz FA, et al. *Crit Rev Oncol Hematol.* 2014;91:248–256. 8. Minner S, et al. *Prostate.* 2011;71:281–288. 9. Liu H, et al. *Cancer Res.* 1998;58:4055–4060. 10. Afshar-Oromieh A, et al. *J Nucl Med.* 2015;56:1697–1705. 11. Violet J, et al. *J Nucl Med.* 2019;60:517–523. 12. Banerjee S, et al. *Chem Rev.* 2015;115:2934–2974. 13. Sartor O, et al. *N Engl J Med.* 2021;385:1091–1103.

PSMAfore Study Design



[a]Patients who are considered appropriate for delaying taxane-based chemotherapy.
[b]Only participants with PSMA-positive cancer and confirmed eligibility (determined by the sponsor's central reader) will be randomized.
ARPI, androgen receptor pathway inhibitor; BPI-SF, Brief Pain Inventory – Short Form questionnaire; CRPC, castration-resistant prostate cancer; DCR, disease control rate; EQ-5D- 5L, EuroQol 5-level, 5-dimension questionnaire; FACT-P, Functional Assessment of Cancer Therapy – Prostate questionnaire; HRQoL, health-related quality of life; HSPC, hormone-sensitive prostate cancer; mCRPC, metastatic castration-resistant prostate cancer; ORR, overall response rate; OS, overall survival; PET/CT, positron emission tomography/computerized tomography; PFS, progression-free survival; PSA, prostate-specific antigen; PSA50, proportion of participants who achieve ≥50% decrease from baseline in PSA confirmed at ≥4 weeks; PSMA, prostate-specific membrane antigen; Q6W, once every 6 weeks; R, randomization; RECIST v1.1, Response Evaluation Criteria in Solid Tumors, version 1.1; rPFS, radiographic PFS.

Planned Analyses

- The primary efficacy and safety analyses will be performed after ~ 156 rPFS events per BICR, to ensure at least a 95% power to detect a hazard ratio of 0.56, assuming a 2.5% significance on a one-sided log-rank test
- Any additional data for patients continuing to receive study treatment after this time point and for those continuing for efficacy follow-up (rPFS, OS) will be further assessed at the time of the final OS analysis, after observing ~ 297 deaths or when statistical significance is reached at any interim OS analysis

BICR, blinded independent central review; OS, overall survival; rPFS, radiographic progression-free survival.

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Study Status

- The first participant was enrolled into the study on June 15, 2021
- Sites across Austria, Belgium, Czech Republic, France, the Netherlands, Poland, Slovakia, Spain, Sweden, Switzerland, United Kingdom, and the United States are currently recruiting patients into the study.
- The estimated study completion is December 2024

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BARCELONA 2024 ESMO congress

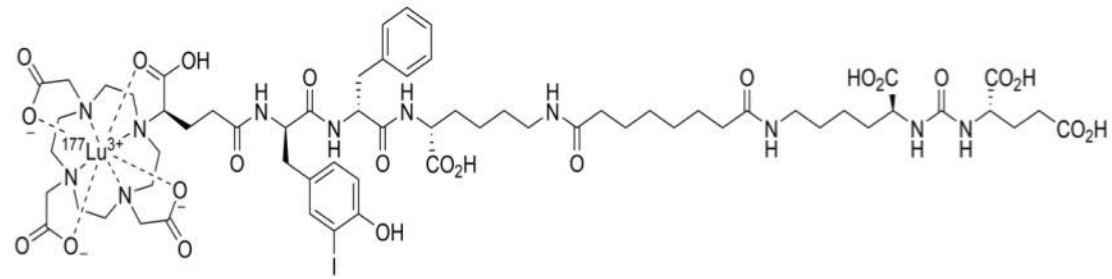
Efficacy of ^{177}Lu-PNT2002 in PSMA-positive mCRPC following progression on an androgen-receptor pathway inhibitor (ARPI) (SPLASH)

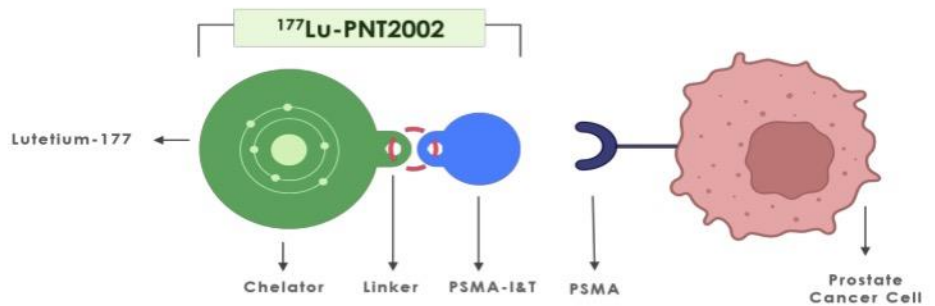
Presenter: Oliver Sartor
Mayo Clinic, Rochester, MN, USA

Co-authors: Di Maria Jiang, Martin Smoragiewicz, Matthew R. Zibelman, Aude Flechon, Ghassan El-Haddad, Gad Abikhzer, Fred Saad, Ronald F. Tutrone, Scott T. Tagawa, Ur Metser, Jeremie Calais, Aaron Richard Hansen, Wenting Wu, Jessica Jensen, Chantal Trieu, Neil E. Fleshner, Iryna Teslenko, Jean-Claude Provost, Kim N. Chi, on behalf of the SPLASH Trial Investigators

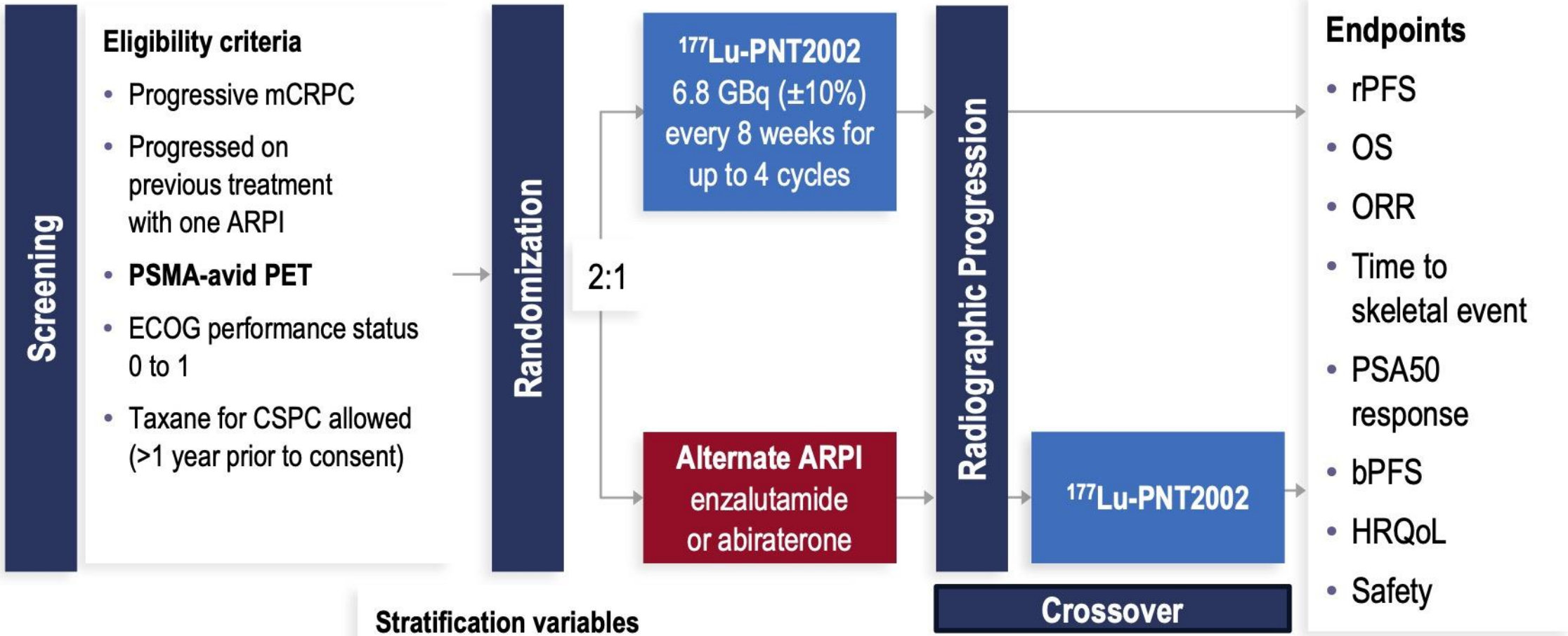
Background

- **^{177}Lu-PNT2002 ([Lu 177]-PSMA-I&T)** is a prostate specific membrane antigen (PSMA)-targeted small molecule radioligand linked to a DOTAGA radiometal chelator
- **SPLASH (NCT04647526)** is a phase III, randomized study to evaluate efficacy and safety of ^{177}Lu-PNT2002 in mCRPC after androgen receptor pathway inhibitor (ARPI) therapy
- **^{177}Lu-PNT2002** delivers PSMA-targeted radiation to prostate cancer cells, causing DNA damage and ultimately cancer cell death

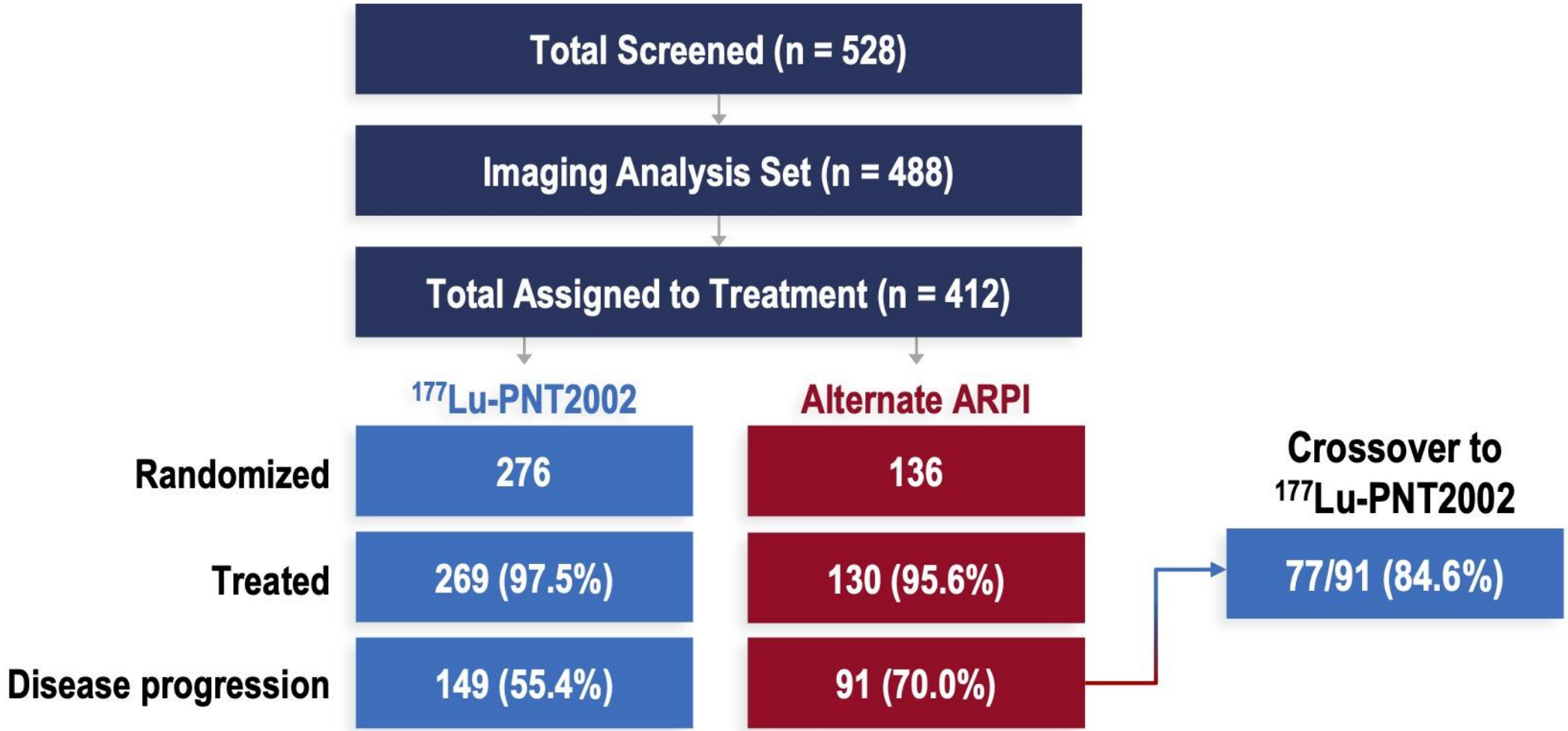




SPLASH study design



Patient Disposition



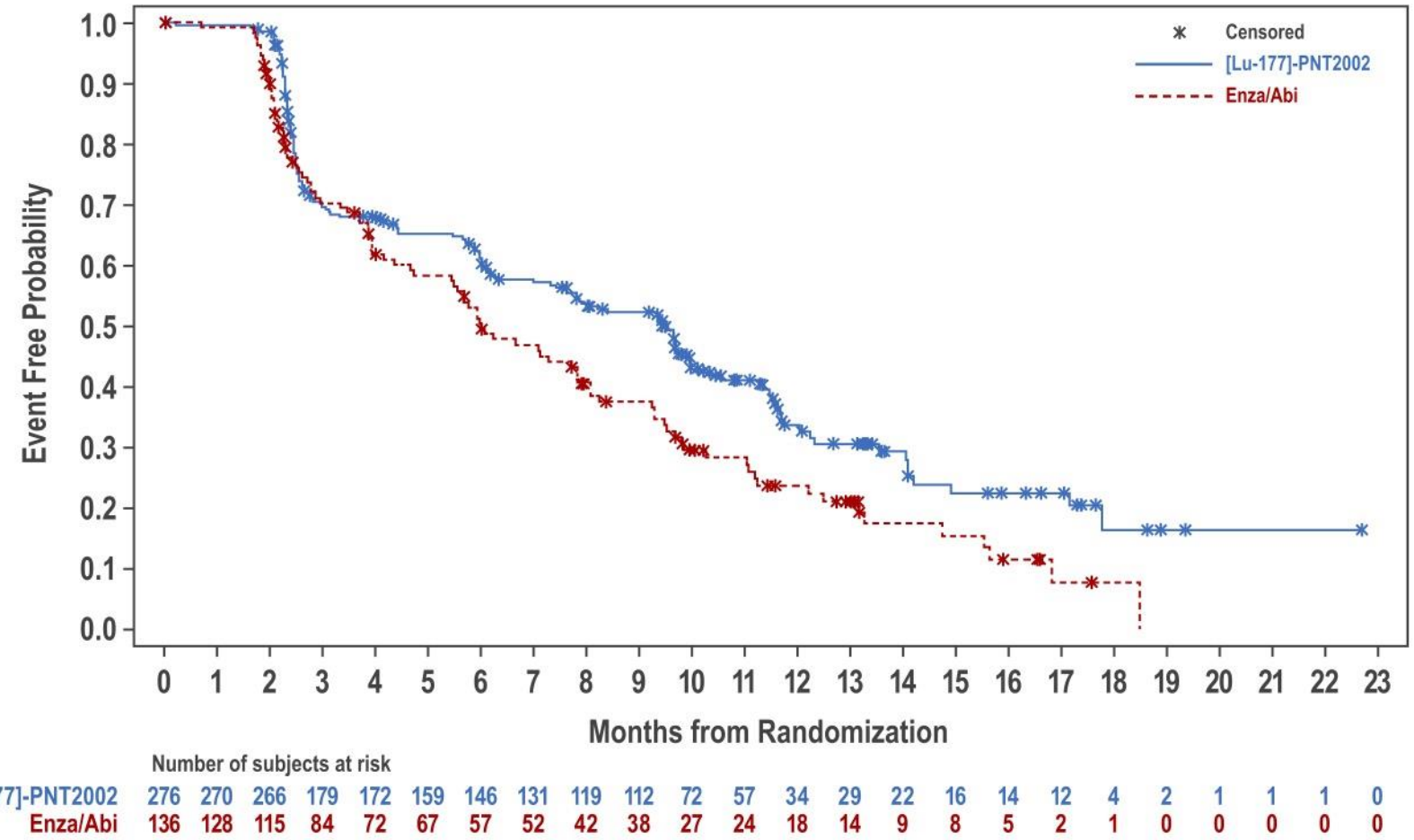
Data Cutoff: 01/NOV/2023

Baseline Patient Characteristics

Parameters	^{177}Lu-PNT2002 (n = 276)	Alternate ARPI (n = 136)
Age, median (range), years	72 (45-92)	72 (47-90)
Race, n (%)		
Black or African American	32 (11.6)	8 (5.9)
White	215 (77.9)	112 (82.4)
ECOG performance status		
0	162 (58.7)	76 (55.9)
1	113 (40.9)	59 (43.3)
PSA, median (range), µg/L	13.20 (0.19-1182)	18.95 (0.33-1528)
Hemoglobin (range), g/L	127 (83-160)	129.5 (84-163)
Alkaline phosphatase (range), U/L	91 (28-1348)	95 (25-1256)
Lactate dehydrogenase (range), U/L	191 (114-1800)	186.5 (84-644)
Prior taxane treatment for CSPC, n (%)		
Yes	49 (17.8)	23 (16.9)
No	227 (82.2)	113 (83.1)
Metastatic status at start of prior ARPI therapy, n (%)		
M0	28 (10.1)	15 (11.0)
M1	248 (89.9)	121 (89.0)

Data Cutoff: 01/NOV/2023

Primary Endpoint - rPFS: Primary Analysis

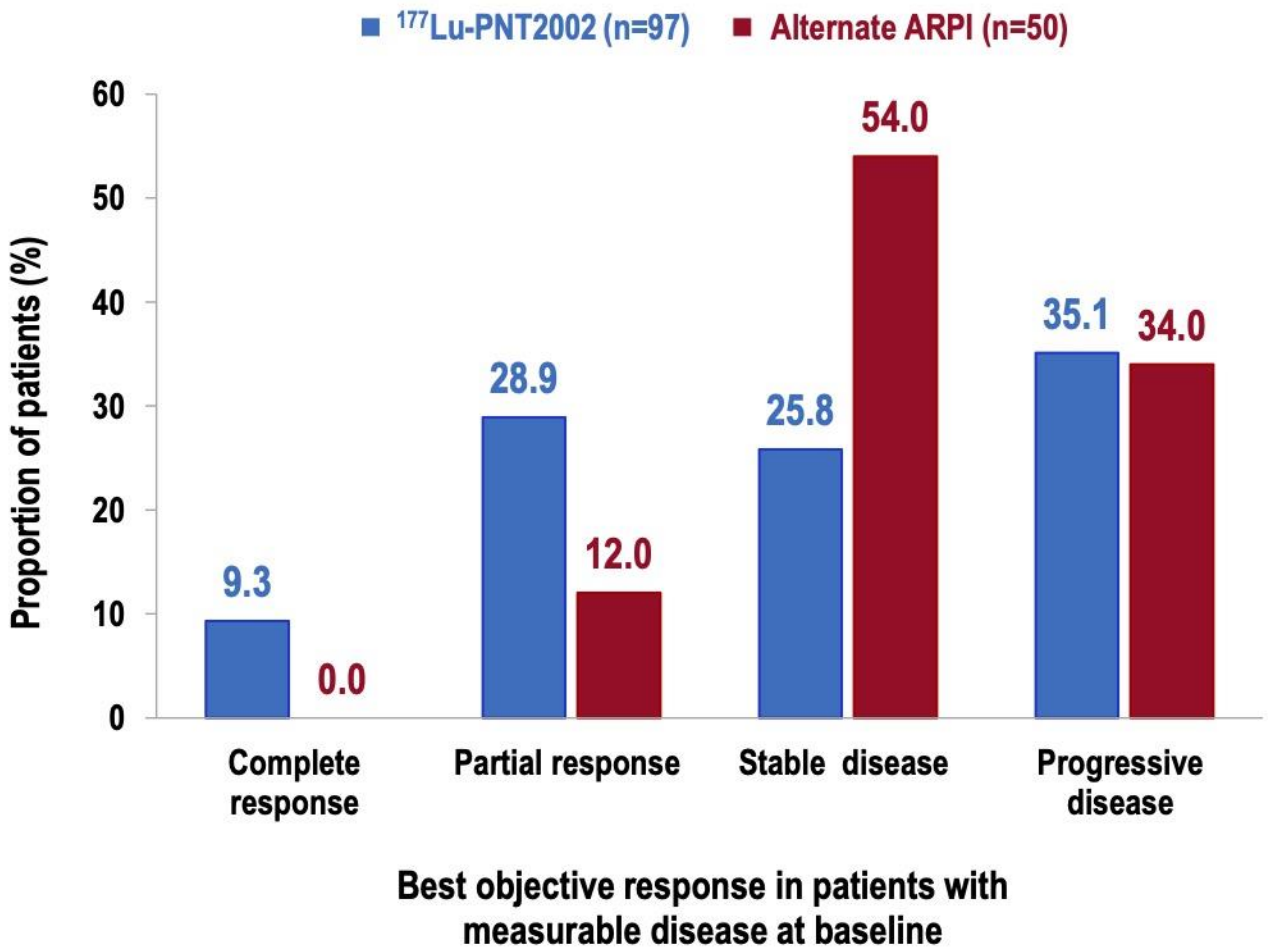


	^{177}Lu-PNT2002 (n = 276)	Alternate ARPI (n = 136)
Events, n	162 (58.7%)	96 (70.6%)
Median rPFS (95% CI)	9.5 months (7.4, 10.0)	6.0 months (4.7, 7.9)
Median follow-up (95% CI)	11.1 months (10.1, 11.6)	12.9 months (10.2, 15.9)

HR: 0.71 (95% CI: 0.55, 0.92)
***p* = 0.0088**

Data Cutoff: 01/NOV/2023

Overall Response Rate

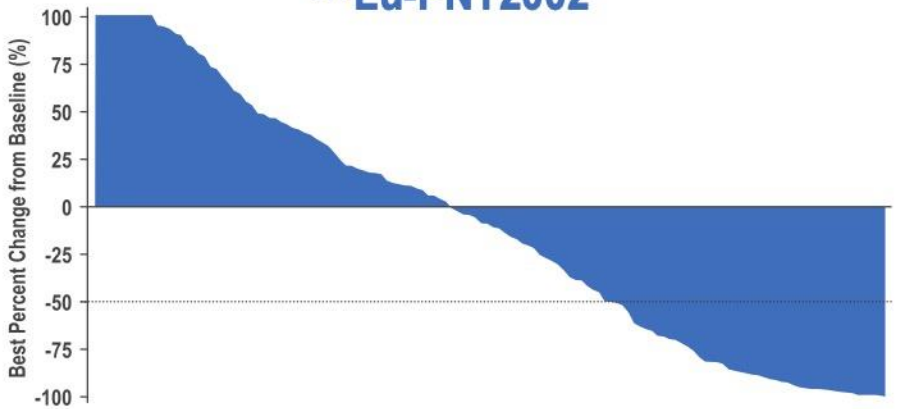


	177Lu-PNT2002	Alternate ARPI	*p*-value
Best Overall Response (95% CI)	38.1% (37/97) (28.5, 48.6)	12% (6/50) (4.5, 24.3)	0.0021
Median DOR (95% CI)	9.4 months (5.9, 13.2)	7.3 months (1.6, NE)	

Data Cutoff: 01/NOV/2023

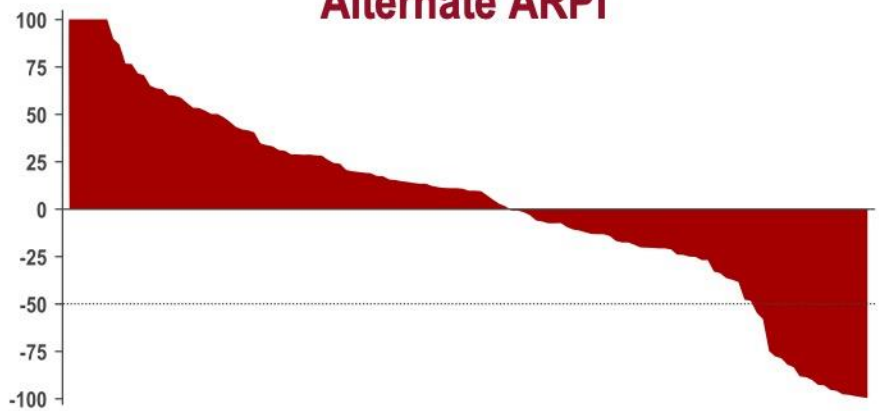
PSA50 Response

^{177}Lu-PNT2002



≥50% decrease: 35.7% (96/269)*

Alternate ARPI



≥50% decrease: 14.6% (19/130)*

*evaluable subjects w/ baseline PSA value

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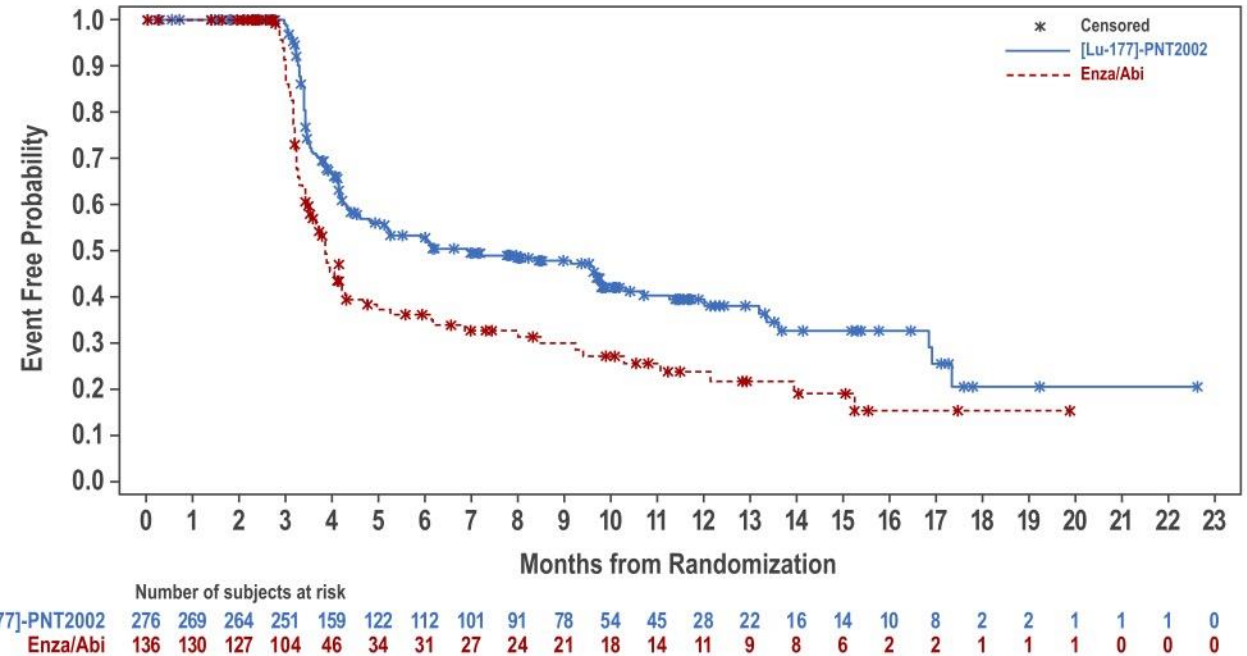
Data Cutoff: 01/NOV/2023

bPFS

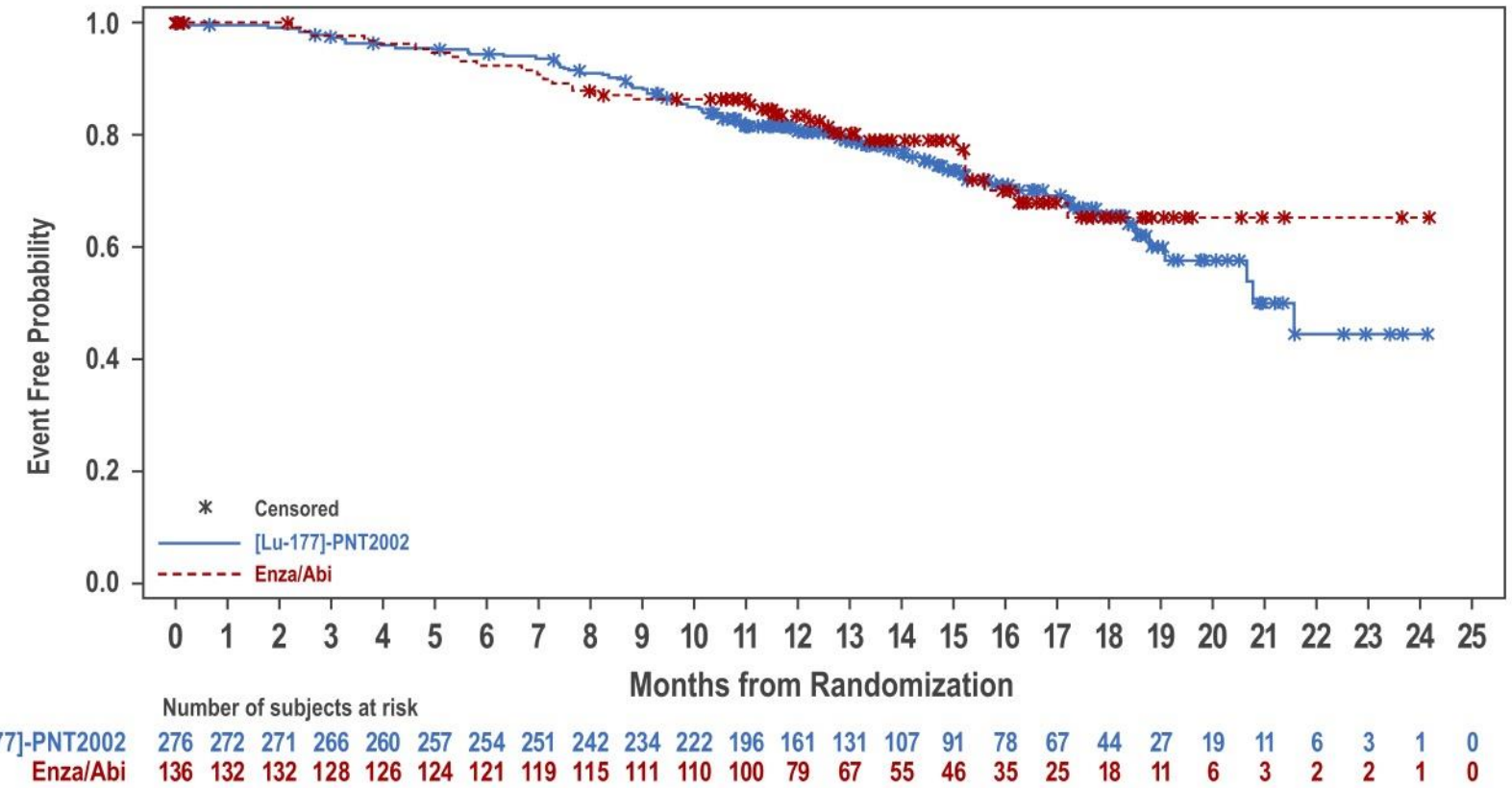


Number of subjects at risk

[Lu-177]-PNT2002	276	269	264	251	159	122	112	101	91	78	54	45	28	22	16	14	10	8	2	2	1	1	1	0
Enza/Abi	136	130	127	104	46	34	31	27	24	21	18	14	11	9	8	6	2	2	1	1	1	0	0	0

	^{177}Lu-PNT2002 (n = 276)	Alternate ARPI (n = 136)
Events, n	143 (51.8%)	82 (60.3%)
Median bPFS (95% CI)	7.0 months (4.8, 9.9)	3.9 months (3.5, 4.3)
Median follow-up (95% CI)	9.9 months (9.4, 10.8)	10.0 months (6.6, 11.6)
HR: 0.58 (95% CI: 0.44, 0.76) *p* **<0.0001**		

1st Interim OS: Intent-to-Treat Analysis



	^{177}Lu-PNT2002 (n = 276)	Alternate ARPI (n = 136)
Median OS	20.8 months (19.1, NE)	NE (NE, NE)

HR: 1.11 (95% CI: 0.73, 1.69); p = 0.6154

- **Overlapping OS KM curves suggests potential violation of the "common treatment effect" assumption in RPSFTM method**

Data Cutoff: 01/NOV/2023

Most Common Treatment-Emergent Adverse Events (≥10%)

	All grades		Grades 3-5	
TEAE, n (%)	^{177}Lu-PNT2002 (n = 269)	Alternate ARPI (n = 130)	^{177}Lu-PNT2002 (n = 269)	Alternate ARPI (n = 130)
Fatigue	144 (53.5)	52 (40.0)	3 (1.1)	4 (3.1)
Dry mouth	100 (37.2)	2 (1.5)	0	0
Nausea	84 (31.2)	25 (19.2)	1 (0.4)	0
Arthralgia	76 (28.3)	36 (27.7)	3 (1.1)	6 (4.6)
Back pain	56 (20.8)	28 (21.5)	8 (3.0)	8 (6.2)
Constipation	54 (20.1)	23 (17.7)	0	0
Anaemia	48 (17.8)	14 (10.8)	15 (5.6)	4 (3.1)
Decreased appetite	40 (14.9)	17 (13.1)	1 (0.4)	0
Diarrhoea	40 (14.9)	13 (10.0)	0	1 (0.8)
Oedema peripheral	30 (11.2)	8 (6.2)	0	0
Pain in extremity	29 (10.8)	17 (13.1)	4 (1.5)	2 (1.5)
Vomiting	28 (10.4)	6 (4.6)	3 (1.1)	0
COVID-19	27 (10.0)	10 (7.7)	1 (0.4)	0

Data Cutoff: 01/NOV/2023

Conclusions

- ^{177}Lu-PNT2002 reduced the risk of radiographic progression or death by 29% vs. ARPI: HR 0.71 (95% CI: 0.55, 0.92); p=0.0088
- OS data continue to mature
- Multiple secondary endpoints favor ^{177}Lu-PNT2002 (ORR, PSA, HRQoL)
- ^{177}Lu-PNT2002 safety profile compared favorably to the ARPI control

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A randomized multicenter open-label phase III trial comparing enzalutamide vs a combination of Radium-223 and enzalutamide in asymptomatic or mildly symptomatic patients with bone metastatic mCRPC

Results of EORTC-GUCG 1333/PEACE-3, an EORTC/CTI/CUOG/LACOG/UNICANCER-GETUG cooperative study

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Oncology Institute of Southern Switzerland, EOC,
Bellinzona, Switzerland

On behalf of A. Choudhury, F. Saad , E. Gallardo Diaz, A. Soares, Y. Loriot, R. McDermott, A. Rodriguez-Vida, P. Isaacsson Velho, F. Nole, F. Cruz, T. Roumeguere, G. Daugaard, R. Yamamura, E. Bompas, P. Maroto, F. Gomez Veiga, I. Skoneczna, K. Martins da Trindade, F. Mavignier Carcano, F. Lecouvet, C.Coens, C. Poncet, B. Fournier, B. Tombal

PEACE Prostate Cancer Consortium Europe

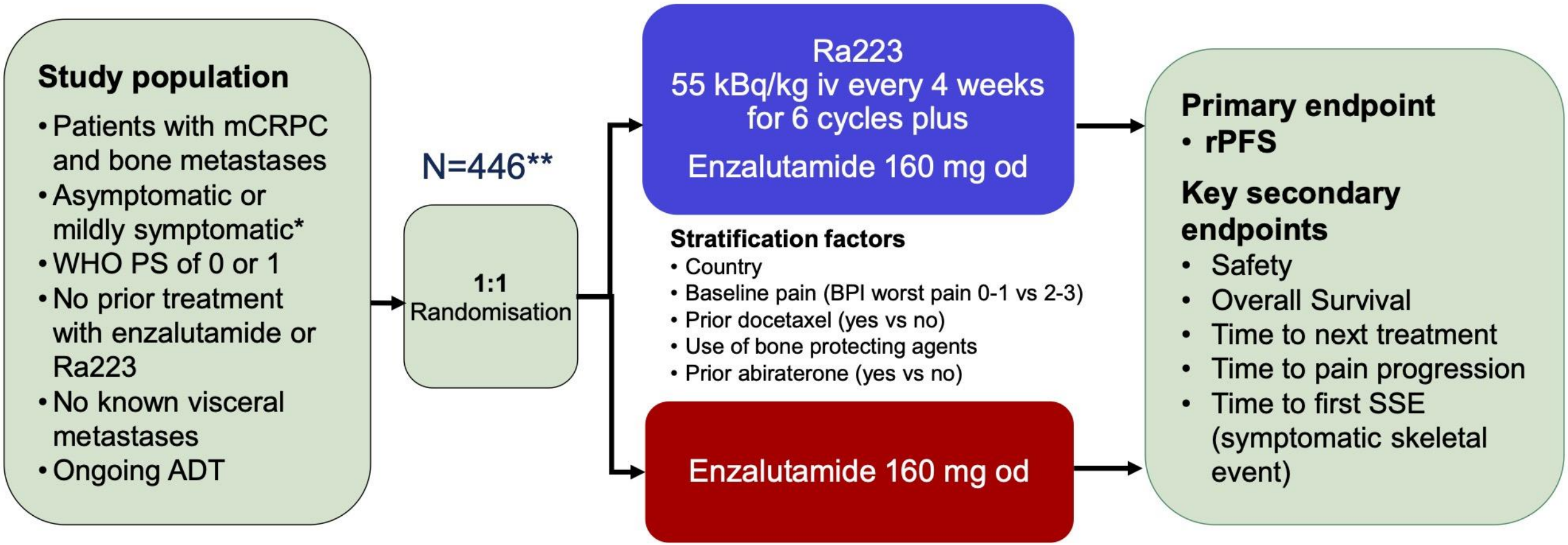
EORTC European Organisation for Research and Treatment of Cancer

Background

- Abiraterone and enzalutamide are standard of care options for 1st line treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) progressing on androgen deprivation therapy (ADT) [1,2]
- No combination so far has been proven to increase radiological progression-free survival (rPFS) **and** overall survival (OS) in first line mCRPC
- Radium-223 dichloride (Ra223) is an alpha particle-emitting calcium mimetic that selectively targets bone metastases and induces double-stranded DNA-breaks[3]
- In the ALSYMPCA trial, Ra223 has been shown to increase OS (HR: 0.7), in an era before the introduction of abiraterone and enzalutamide[4]
- The ERA-223 trial tested the combination of abiraterone plus Ra223 versus abiraterone plus placebo. The combination did not show a benefit in symptomatic skeletal event-free survival or OS and was associated with an increase in fractures[5]

(1) Ryan CJ et al. N Engl J Med 2013; (2) Beer TM et al .N Engl J Med 2014; (3) Morris MJ et al. Nat Rev Urol 2019; (4) Parker C et al. N Engl J Med 2013; (5) Smith M et al. Lancet Oncol 2019

EORTC-GUCG 1333 (PEACE-3)



*defined as brief pain inventory WP24 score < 4
** original target accrual N=560, adapted for slow accrual

Use of bone protecting agents (BPA) made mandatory
(after inclusion of 119 patients)

Baseline characteristics

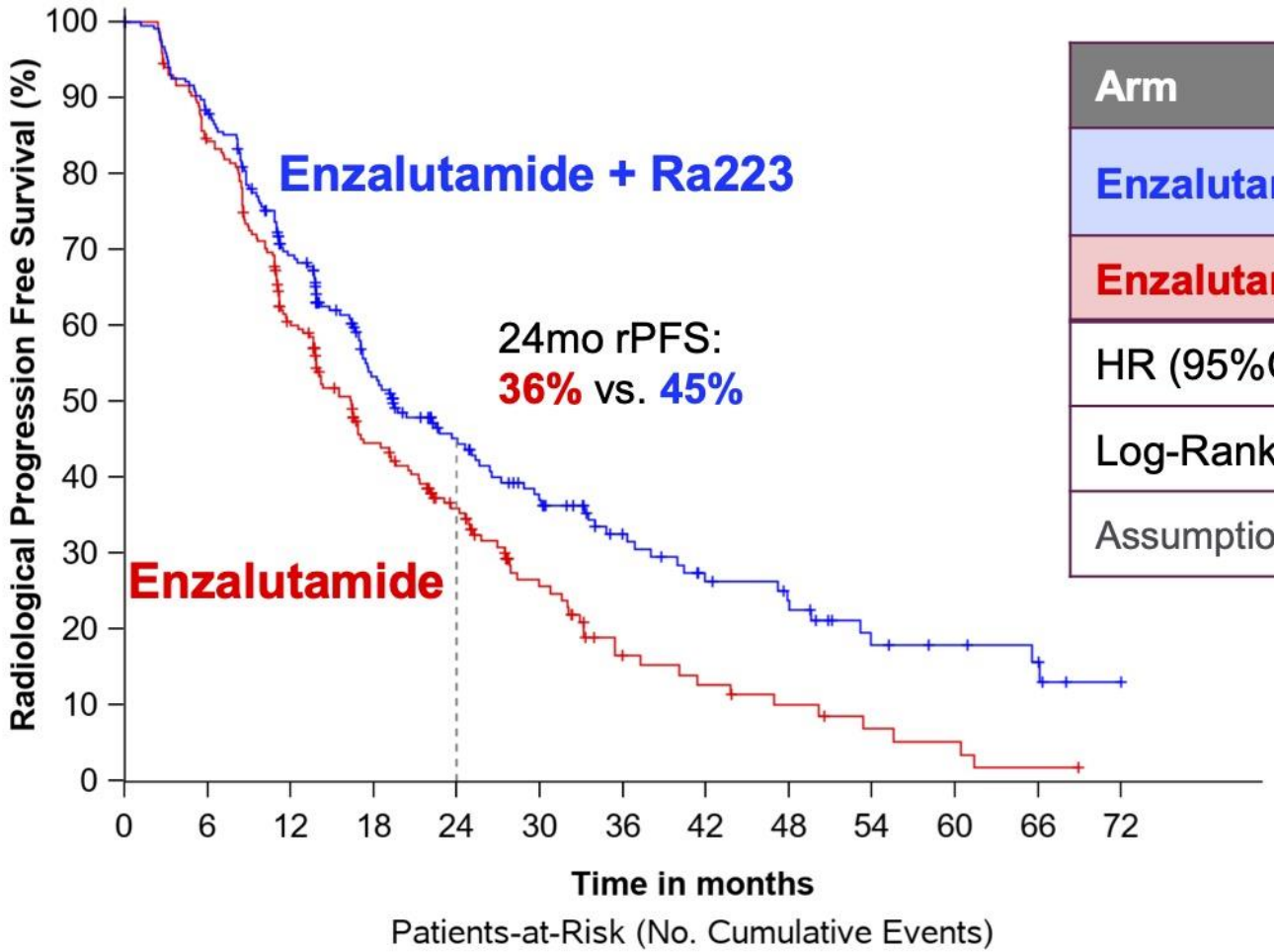
446 patients enrolled in 12 countries, 11/2015 to 03/2023, median follow-up: 42.2 months

	Enza+Ra223 (N=222)	Enza (N=224)
	N (%)	N (%)
Age, Median (range) years	70.0 (43.0 - 90.0)	70.0 (47.0 - 90.0)
PSA, Median (Q25-Q75) ng/mL	25.3 (6.5 - 68.8)	23.0 (8.5 - 54.9)
WHO Performance status 0	152 (69)	154 (69)
Prior docetaxel(1)	67 (30.2)	66 (30)
Prior abiraterone(1)	4 (2)	7 (3)
Bone lesions(2)		
<10	109 (49)	105 (47)
≥10	93 (42)	99 (44)
Missing or diffuse lesions	20 (9)	20 (9)
Alkaline phosphatase		
≤ULN	127 (57)	107 (48)
>ULN	82 (37)	110 (49)
Missing	13 (6)	7 (3)
Extra-skeletal disease at baseline	77 (35)	73 (33)

(1) Prior docetaxel or abiraterone was allowed for mHSPC

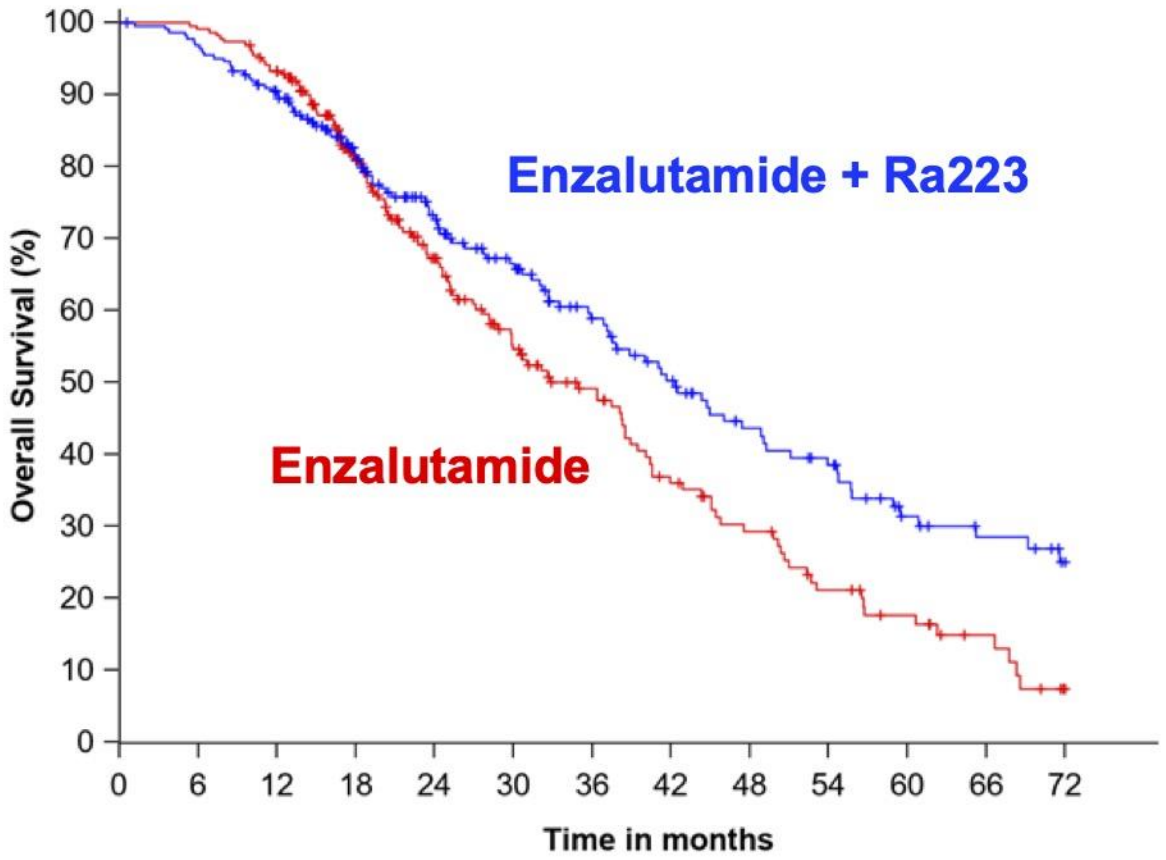
(2) Per imaging guidelines, the type of bone lesions is reported by a radiologist and classified into focal, diffuse or equivocal. Only focal bone lesions can be counted.

Primary endpoint: rPFS



Arm	n/N	Median (95%CI)
Enzalutamide + Ra223	139/222	**19.4** (17.1-25.3) mo
Enzalutamide	160/224	**16.4** (13.8-19.2) mo
HR (95%CI)	**0.69** (0.54-0.87)	
Log-Rank p-value	**0.0009**	
Assumption of proportional hazard achieved		

Overall Survival at interim analysis (80% of OS events)



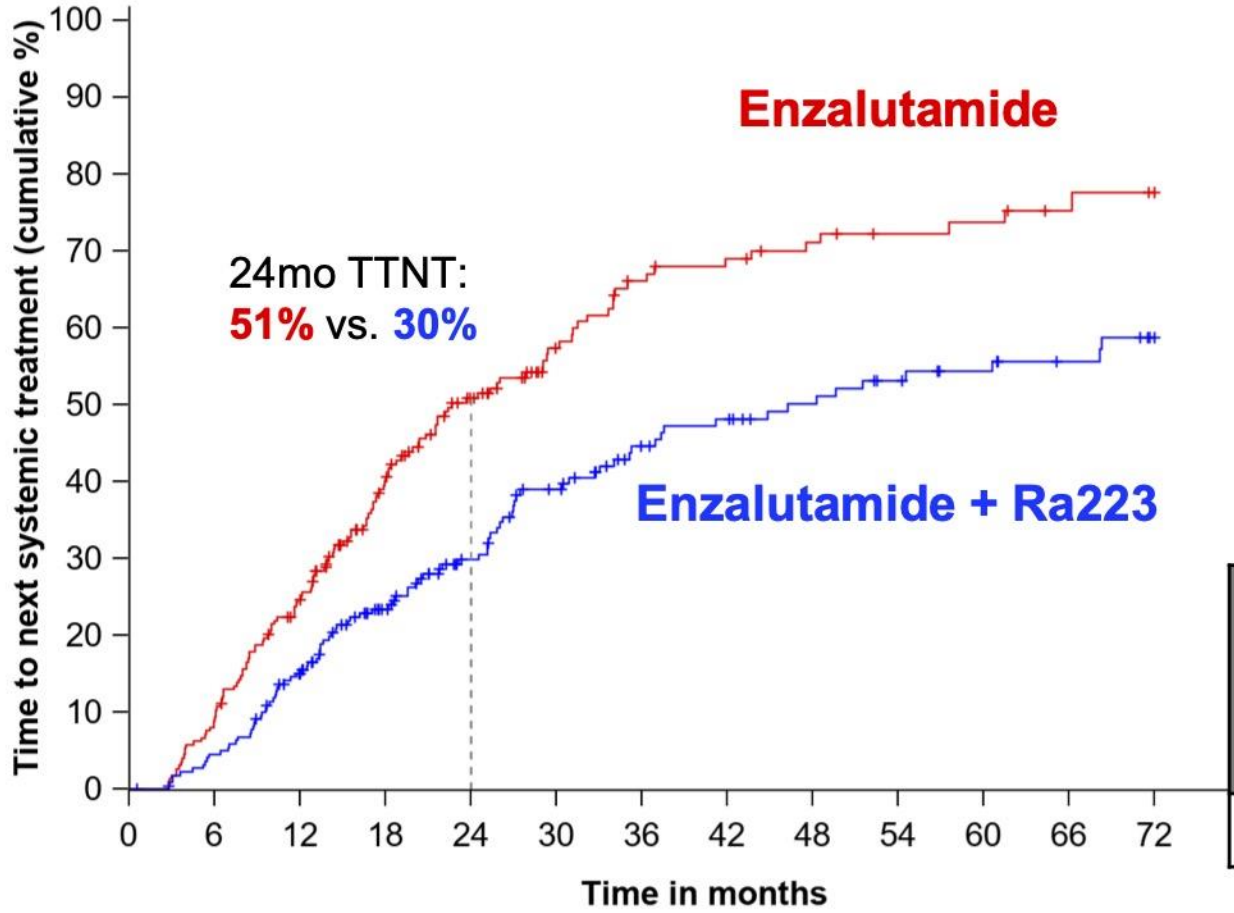
Patients-at-Risk (No. Cumulative Events)

Enza-	224 (0)	206 (15)	107 (64)	58 (90)	30 (112)	14 (123)	1 (129)
Enza+Ra223-	222 (0)	194 (21)	114 (53)	71 (73)	43 (90)	23 (101)	12 (105)

Arm	n/N	Median (95%CI)
Enzalutamide + Ra223	110/222	**42.3** (36.8-49.1) mo
Enzalutamide	129/224	**35.0** (28.8-38.9) mo
HR (95%CI)	**0.69** (0.52-0.90)	
Log-Rank p-value	**0.0031**	<0.0034

- Pre-set level of significance for interim analysis was ≤ 0.0034
- Due to non-proportional hazards plus lack of unequivocal significance for RMST (restricted mean survival time) sensitivity analysis, study will continue to final OS analysis

Time to next systemic treatment



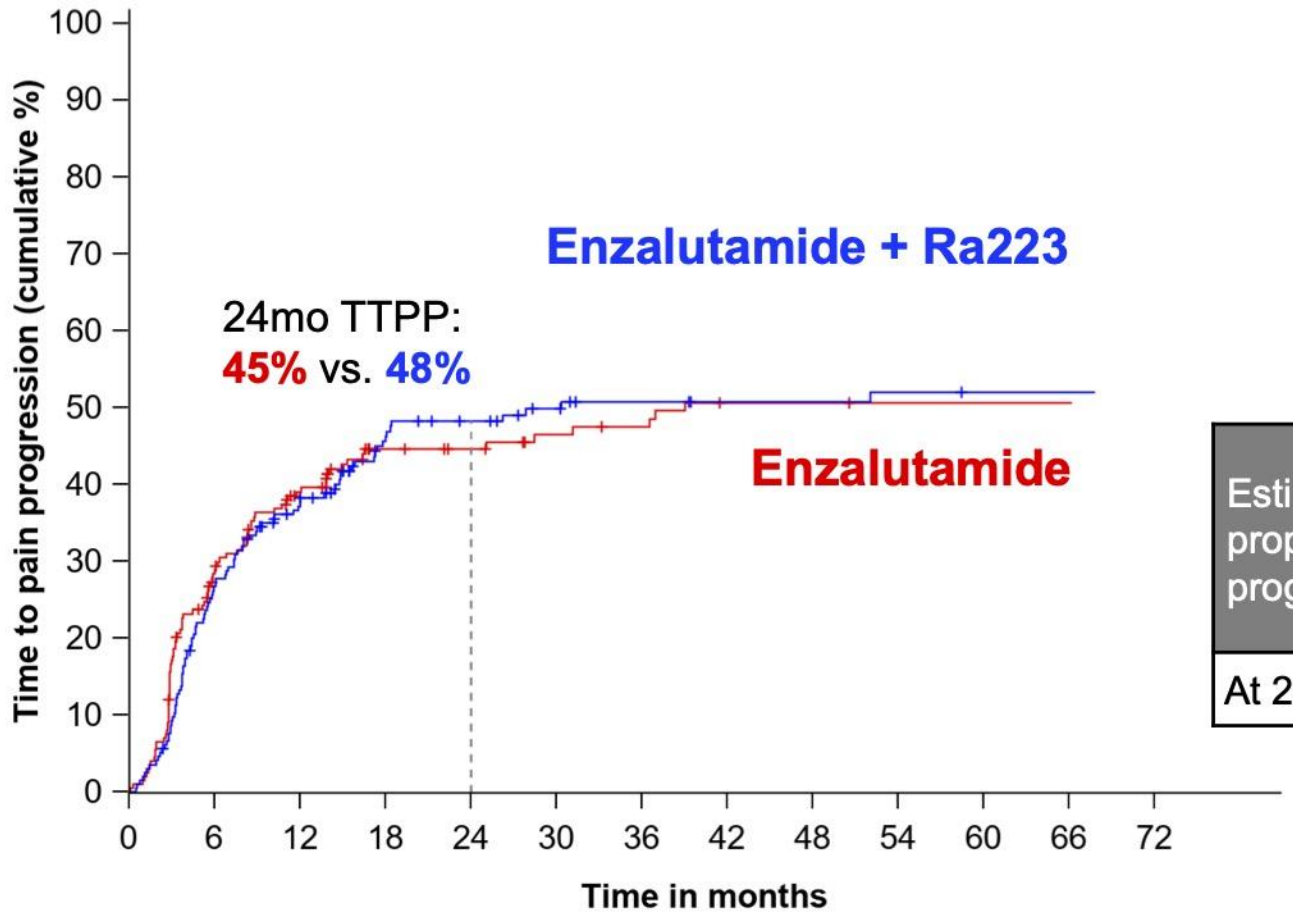
Patients-at-Risk (No. Cumulative Events)

Enza-	224 (0)	156 (55)	62 (105)	22 (124)	11 (129)	6 (131)	1 (133)
Enza+Ra223-	222 (0)	166 (33)	87 (61)	45 (81)	30 (87)	16 (91)	6 (94)

Hazard ratio	Fine&Gray p-value
0.57 (0.44-0.75)	**<0.0001**

Estimate of proportion started next systemic treatment	Enza+Ra223 (N=222)	Enza (N=224)
	% (95% CI)	
At 24 months	**29.9** (23.6-36.4)	**50.9** (43.6-57.6)

Time to pain progression

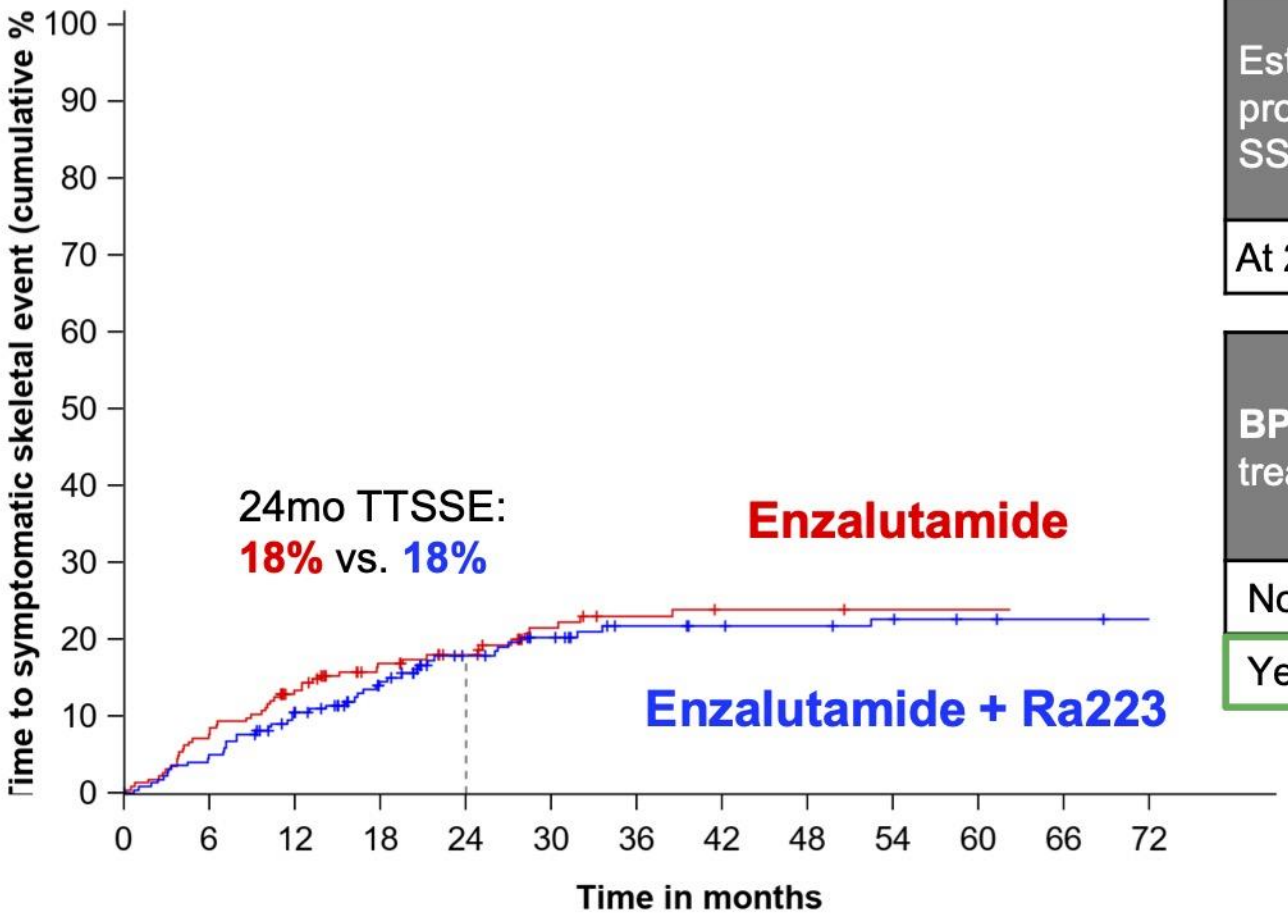


Hazard ratio	Fine&Gray p-value
1.02 (0.77-1.36)	0.5341

Estimate of proportion with pain progression	Enza+Ra223 (N=206)*	Enza (N=203)*
	% (95% CI)	
At 24 months	**48.3** (40.8 - 55.3)	**44.6** (37.3 - 51.6)

*37 patients excluded:
- 35 with opioid use at study entry
- 2 with BPI WP24 pain score ≥ 9 at study entry

Time to symptomatic skeletal event



Patients-at-Risk (No. Cumulative Events)

Enza-	224 (0)	126 (30)	46 (39)	14 (46)	5 (47)	1 (47)	0 (47)
Enza+Ra223-	222 (0)	141 (23)	60 (37)	29 (43)	18 (43)	8 (44)	3 (44)

Estimate of proportion with a SSE	Enza+Ra223 (N=222)	Enza (N=224)
	% (95% CI)	
At 24 months	**17.8** (12.9 - 23.4)	**18.0** (13.2 – 23.4)

BPA use during treatment	Enza+Ra223 (N=222)	Enza (N=224)
	N (%)	
No (or after fracture)	41 (18.5)	35 (15.6)
Yes	181 (81.5)	189 (84.4)

Hazard ratio	No formal comparison as previous endpoint was not significant
0.93 (0.62 - 1.38)	

Safety (2)

Most common grade 3-5 treatment emergent AE (TEAE)	Enza+Ra223 (N=218)	Enza (N=224)
	N (%)	N (%)
All		
Hypertension	73 (33.5)	77 (34.4)
Fatigue	12 (5.5)	4 (1.8)
Fracture	11 (5.1)	3 (1.3)
Anaemia	10 (4.6)	5 (2.2)
Neutropenia	10 (4.6)	0
Bone Pain	9 (4.1)	11 (4.9)
Weight Decreased	7 (3.2)	1 (0.4)
Spinal Cord Compression	6 (2.8)	8 (3.6)
Treatment related		
Hypertension	25 (11.5)	27 (12.1)
Fatigue	9 (4.1)	3 (1.3)
Anaemia	6 (2.8)	0
Neutropenia	7 (3.2)	0

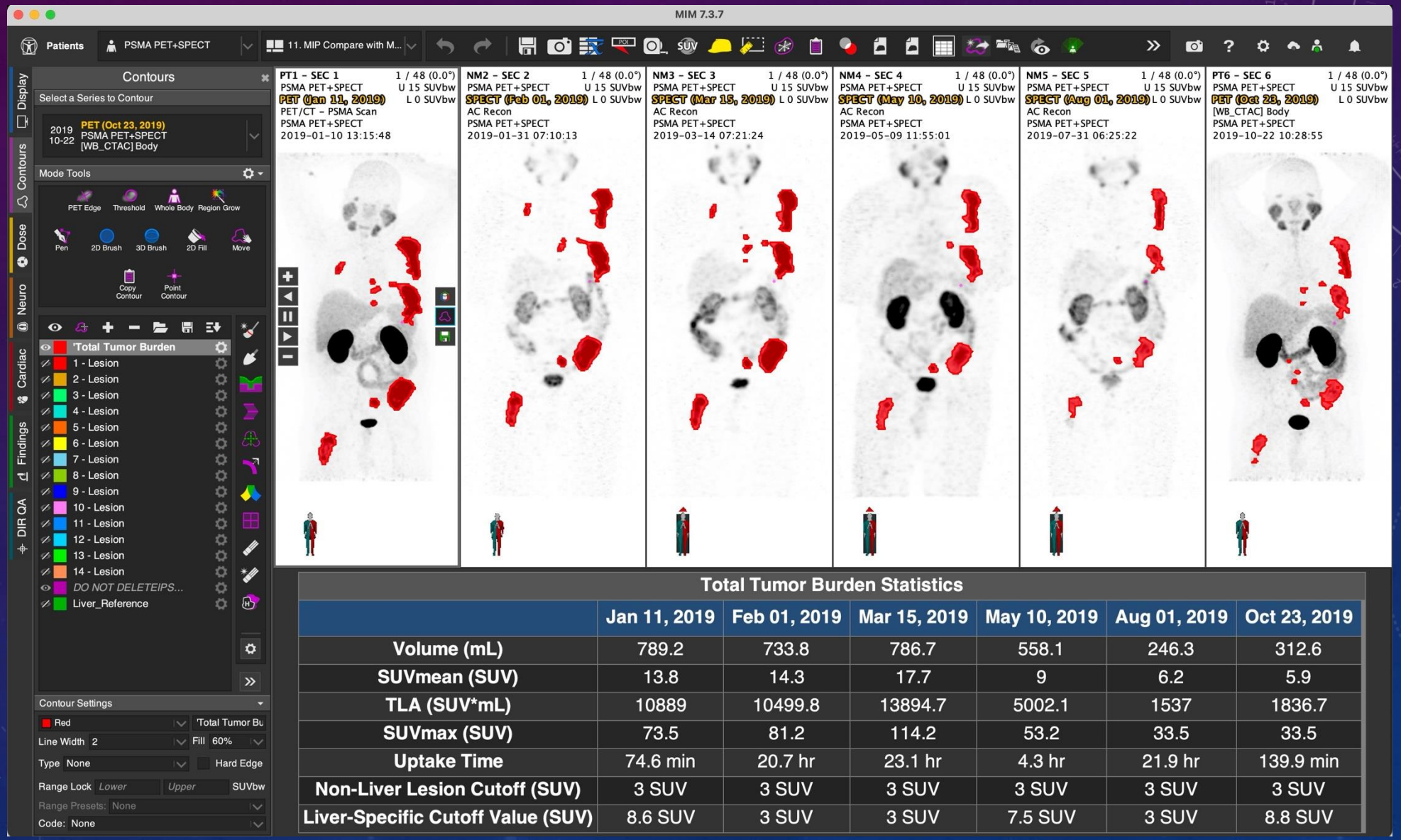
Side effects of special interest: 1 MDS, 1 AML and 1 CML in the combination arm

Conclusions

- Combination of enzalutamide and 6 cycles of Ra223 shows a statistically significant improvement in rPFS
  - HR of 0.69 (p=0.0009)
  - Median rPFS increased from 16.4 months with enzalutamide to 19.4 months with the combination
- Improvement in rPFS supported by a significantly improved OS (HR 0.69, p=0.0031)
  - Due to non-proportional hazards this will be tested further in the final OS analysis to confirm and further characterise the result
- Improvement in rPFS is also supported by a statistically significant improvement in time to next systemic treatment (HR 0.57, p<0.0001)
- Drug related ≥ grade 3 adverse events increased from 19% to 28% in the combination arm

These results support the combination of enzalutamide plus Ra223 (plus a bone protecting agent) as a potential new first line mCRPC treatment option for patients with prostate cancer and bone metastases who have not received a prior androgen-receptor pathway inhibitor

FUTURE PRECISION MEDICINE WILL BE QUANTITATIVE



Total Tumor Burden Statistics

	Jan 11, 2019	Feb 01, 2019	Mar 15, 2019	May 10, 2019	Aug 01, 2019	Oct 23, 2019
Volume (mL)	789.2	733.8	786.7	558.1	246.3	312.6
SUVmean (SUV)	13.8	14.3	17.7	9	6.2	5.9
TLA (SUV*mL)	10889	10499.8	13894.7	5002.1	1537	1836.7
SUVmax (SUV)	73.5	81.2	114.2	53.2	33.5	33.5
Uptake Time	74.6 min	20.7 hr	23.1 hr	4.3 hr	21.9 hr	139.9 min
Non-Liver Lesion Cutoff (SUV)	3 SUV	3 SUV	3 SUV	3 SUV	3 SUV	3 SUV
Liver-Specific Cutoff Value (SUV)	8.6 SUV	3 SUV	3 SUV	7.5 SUV	3 SUV	8.8 SUV

SUMMARY

- Newer radiotracers are imaging receptor expression rather than physiologic processes (like metabolism).
- PSMA PET/CT has changed the standard of care for prostate cancer imaging.
- Theranostics is a powerful targeted therapeutic option, and we are learning how to optimally implement and develop personalized treatments for patients. Quantitative imaging and dosimetry analysis are likely to play a larger role in the future.
- Current theranostic clinical trials reflect the importance of radiopharmaceutical therapy for cancer care. This is reshaping the overall practice of nuclear medicine as our field continues to evolve.

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THANK YOU! – QUESTIONS?