

# How to implement PSMA-based RNT in Belgium

Karolien Goffin – Carlos Artigas – Nadia Withofs  
Nuclear Medicine

[bmuc.be/bmuc2024](https://bmuc.be/bmuc2024)



**11<sup>th</sup> Belgian Multidisciplinary  
Meeting on Urological Cancers**

# Question 1

- Do you have access to Lu-based PSMA RNT for your patients?
  - Answer 1: Yes, in my own hospital
  - Answer 2: Yes, through collaboration in another hospital
  - Answer 3: No



# Question 2

- In your opinion, which clinical scenario is optimal for Lu-PSMA RNT?
  - Answer 1: mCRPC, post-ARPI, post-docetaxel, post-cabazitaxel
  - Answer 2: mCPRC, post-ARPI, post-docetaxel
  - Answer 3: mCRPC, post-ARPI
  - Answer 4: mHSPC



# Sequencing of PSMA-based RNT

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[bmuc.be/bmuc2024](https://bmuc.be/bmuc2024)



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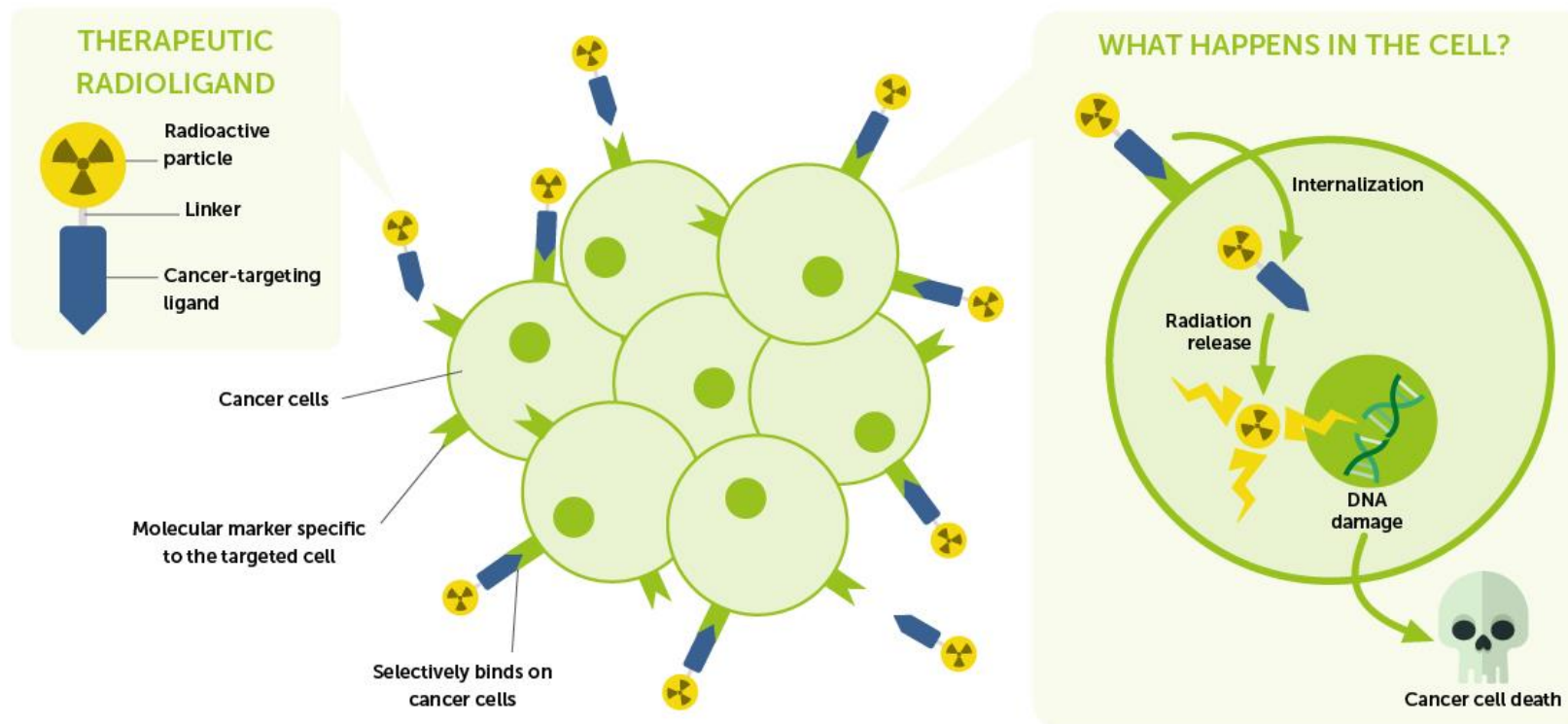
# Conflicts of interest

- I have the following potential conflict(s) of interest to report

Type of affiliation / financial interest	Name of commercial company
Receipt of grants/research supports:	
Receipt of honoraria or consultation fees:	Bayer, Blue Earth Diagnostics, GE Healthcare, Telex, PSI CRO, Novartis, MSD
Participation in a company sponsored speaker's bureau:	Bayer, Telex, Novartis
Stock shareholder:	
Spouse/partner:	
Other support (please specify):	



# How do radioligands work in cancer therapy?



## ADVANTAGES



Targeted therapy



Precise radiation delivery

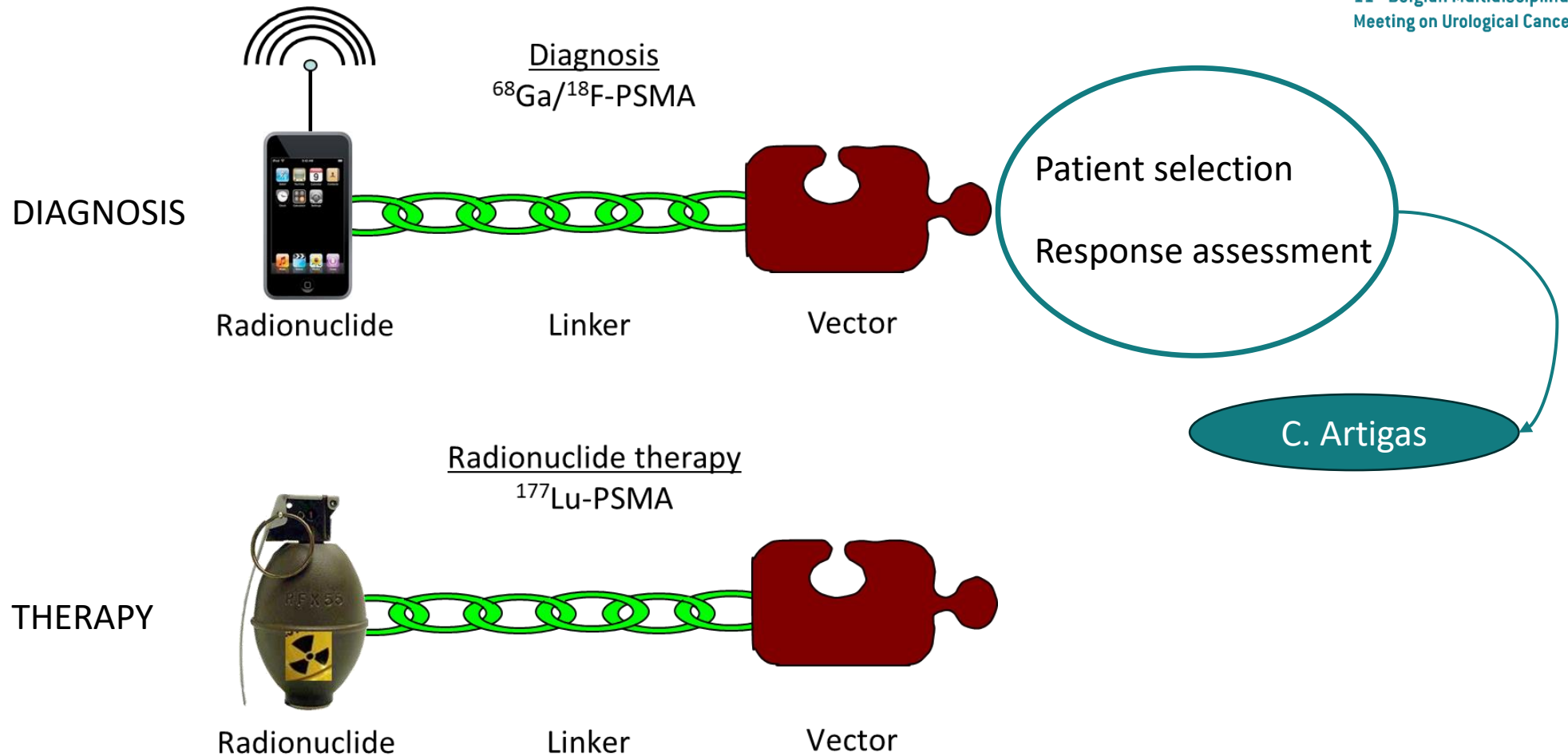


Few side-effects



Can be complemented by precise imaging

# Theranostic duo in prostate cancer



# <sup>177</sup>Lu-PSMA therapy: VISION

International, open-label, phase 3 trial

Patient population

## mCRPC

- At least 1 prior NAAD
- At least 1 prior taxane
- PS = 0-2
- PSMA PET+

N=831

Stratification factors

- LDH (above/below 260)
- Liver mets (Y/N)
- PS (0-1/2)
- NAAD as BSC (Y/N)

2:1 randomization

- **Best SOC**
- **<sup>177</sup>Lu-PSMA-617 7.4 GBq q6 wks x4-6**

N=551

## Primary endpoints

- Overall survival
- rPFS (PCWG3)

- **Best SOC**

N=280

## Centrally read PSMA PET imaging criteria

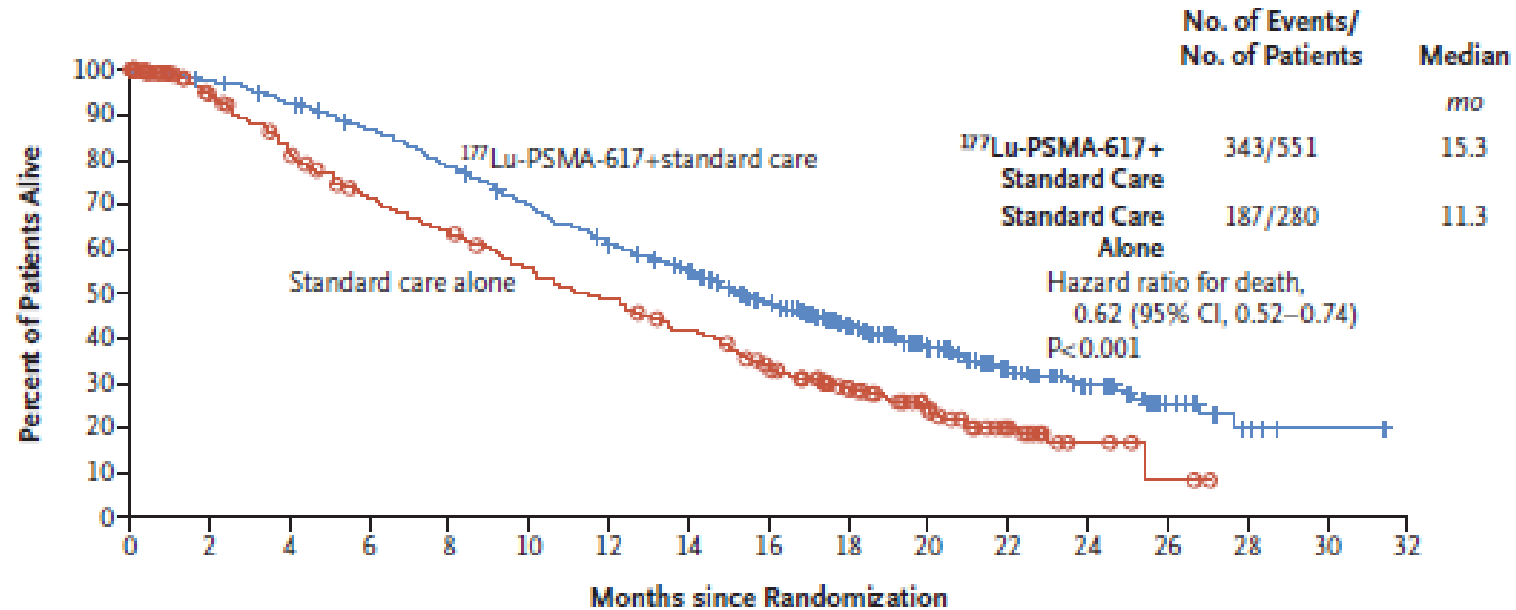
- ≥ 1 PSMA-positive metastatic lesion
  - Positive = <sup>68</sup>Ga-PSMA-11 uptake > liver
- No PSMA-negative metastatic lesions
  - Bone with soft tissue component ≥ 1.0 cm
  - Lymph node ≥ 2.5 cm
  - Solid organ ≥ 1.0 cm

12% excluded



# <sup>177</sup>Lu-PSMA therapy: VISION

## Overall Survival



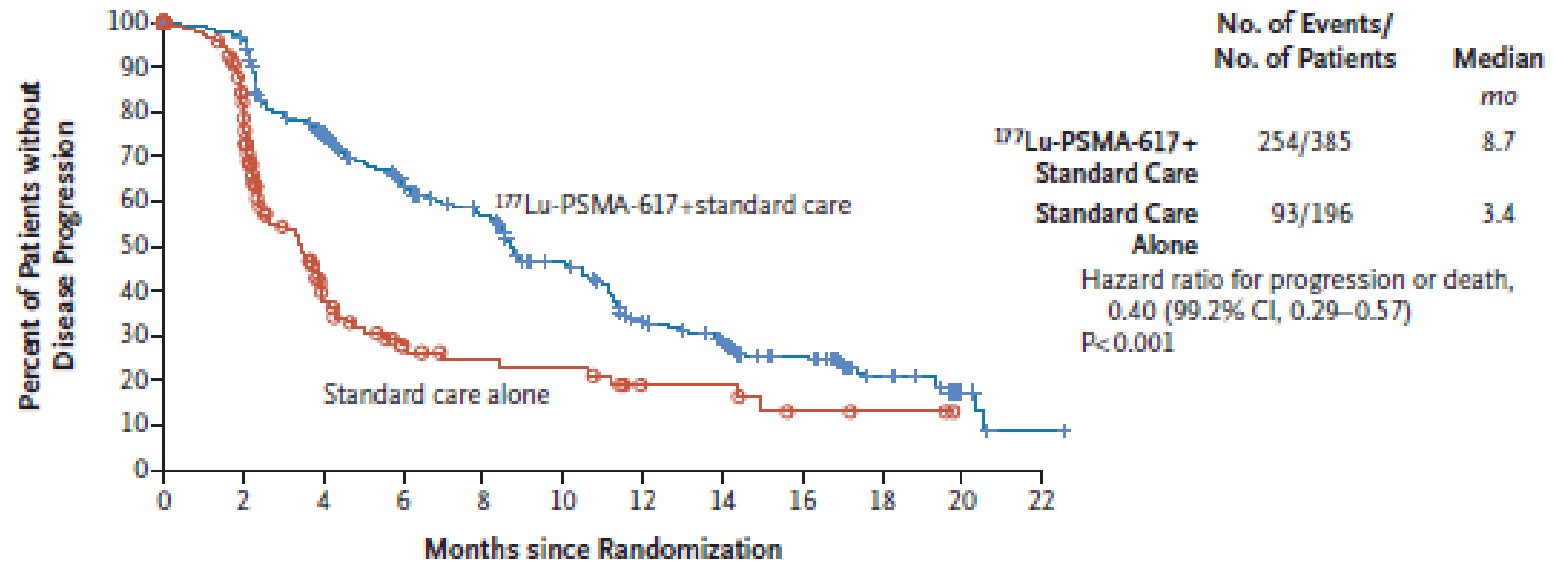
### No. at Risk

<sup>177</sup> Lu-PSMA-617+standard care	551	535	506	470	425	377	332	289	236	166	112	63	36	15	5	2	0
Standard care alone	280	238	203	173	155	133	117	98	73	51	33	16	6	2	0	0	0

**38% reduced risk of death**

# $^{177}\text{Lu}$ -PSMA therapy: VISION

Imaging-Based Progression-free Survival



No. at Risk

$^{177}\text{Lu}$ -PSMA-617+standard care	385	362	272	215	182	137	88	71	49	21	6	1
Standard care alone	196	119	36	19	14	13	7	7	3	2	0	0

**60% reduced risk of progression**

# <sup>177</sup>Lu-PSMA therapy: VISION

**Table 2. Adverse Events.\***

Event	<sup>177</sup> Lu-PSMA-617 plus Standard Care (N=529)		Standard Care Alone (N=205)	
	All Grades	Grade ≥3	All Grades	Grade ≥3
	<i>number of patients (percent)</i>			
Any adverse event	519 (98.1)	279 (52.7)	170 (82.9)	78 (38.0)
Adverse event that occurred in >12% of patients				
Fatigue	228 (43.1)	31 (5.9)	47 (22.9)	3 (1.5)
Dry mouth	205 (38.8)	0	1 (0.5)	0
Nausea	187 (35.3)	7 (1.3)	34 (16.6)	1 (0.5)
Anemia	168 (31.8)	68 (12.9)	27 (13.2)	10 (4.9)
Back pain	124 (23.4)	17 (3.2)	30 (14.6)	7 (3.4)
Arthralgia	118 (22.3)	6 (1.1)	26 (12.7)	1 (0.5)
Decreased appetite	112 (21.2)	10 (1.9)	30 (14.6)	1 (0.5)
Constipation	107 (20.2)	6 (1.1)	23 (11.2)	1 (0.5)
Diarrhea	100 (18.9)	4 (0.8)	6 (2.9)	1 (0.5)
Vomiting	100 (18.9)	5 (0.9)	13 (6.3)	1 (0.5)
Thrombocytopenia	91 (17.2)	42 (7.9)	9 (4.4)	2 (1.0)
Lymphopenia	75 (14.2)	41 (7.8)	8 (3.9)	1 (0.5)
Leukopenia	66 (12.5)	13 (2.5)	4 (2.0)	1 (0.5)
Adverse event that led to reduction in <sup>177</sup> Lu-PSMA-617 dose	30 (5.7)	10 (1.9)	NA	NA
Adverse event that led to interruption of <sup>177</sup> Lu-PSMA-617†	85 (16.1)	42 (7.9)	NA	NA
Adverse event that led to discontinuation of <sup>177</sup> Lu-PSMA-617‡	63 (11.9)	37 (7.0)	NA	NA
Adverse event that led to death‡	19 (3.6)	19 (3.6)	6 (2.9)	6 (2.9)

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## ***<sup>177</sup>Lu-PSMA therapy: VISION***

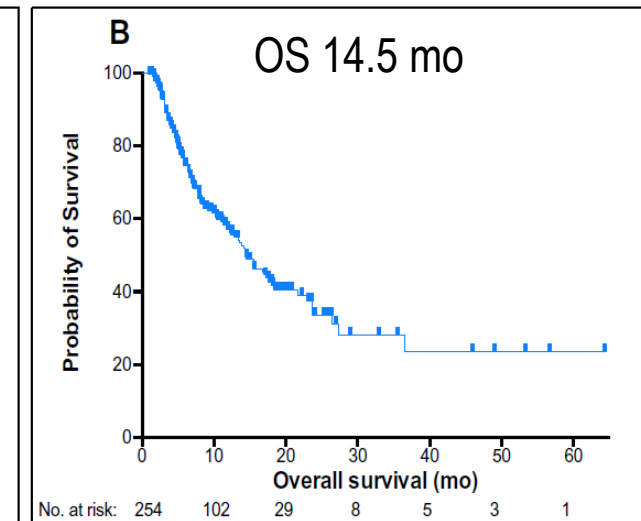
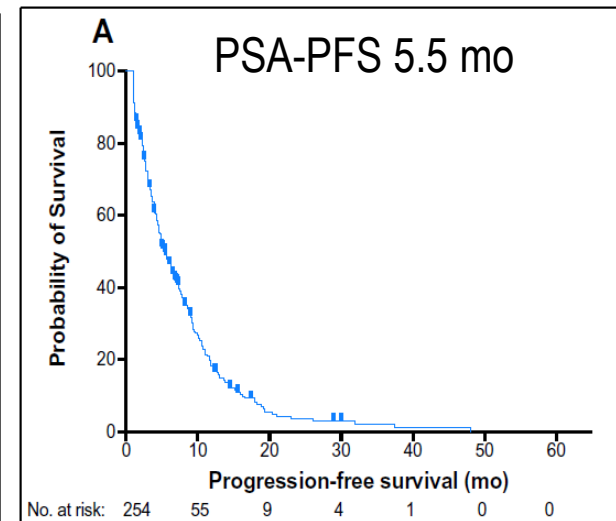
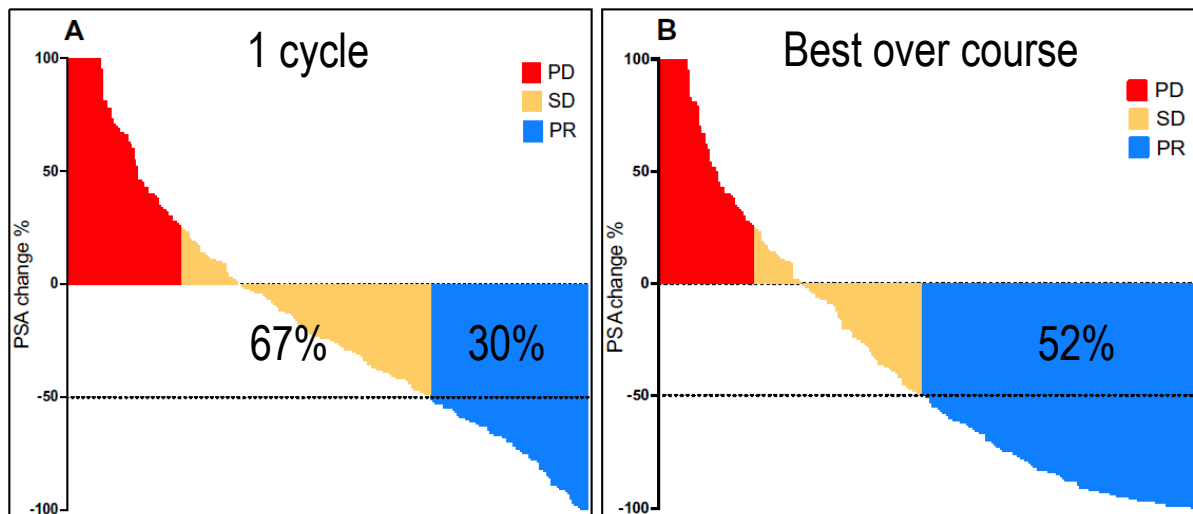
- ✓ OS benefit
- ✓ mCRPC (prior NAAD & taxane)
- ✓ Acceptable toxicity
  - ✓ Low incidence of AEs leading to reduction of activity, interruption or discontinuation of treatment



# Is the VISION also the REALITY?

- REALITY

- Prospective registry, Homburg, Germany
- 254 mCRPC patients
- Elderly (mean age 70 y), heavily pretreated (74% prior taxanes), late end-stage (33% visceral metastases)
- 3 cycles every 5.7 wks



# TheraP: $^{177}\text{Lu}$ -PSMA vs cabazitaxel

multicentre, open-label, phase 2 trial

Patient population

Stratification factors

## mCRPC

- Post docetaxel
- Progressive disease with rising PSA and PSA  $\geq$  20
- ECOG PS = 0-2
- PSMA PET+

N=291

- Disease burden (>20 sites vs  $\leq$  20 sites)
- Prior enza or abi
- Study site

1:1 randomization

- $^{177}\text{Lu}$ -PSMA-617  
8.5 GBq (-0.5 GBq each cycle)  
q6 wks x4-6  
N=99

## Primary endpoints

- PSA decline  $\geq$  50%

- Cabazitaxel  
20 mg/m<sup>2</sup> IV q3 weekly  
up to 10 cycles  
N=101

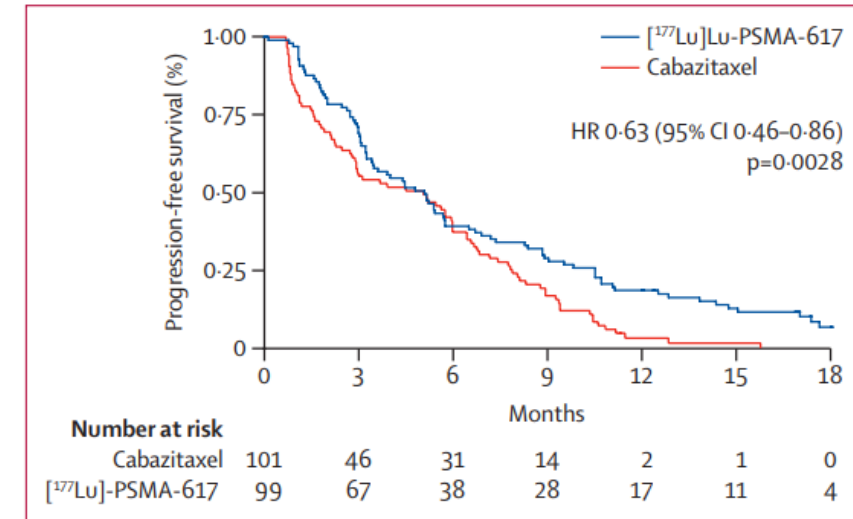
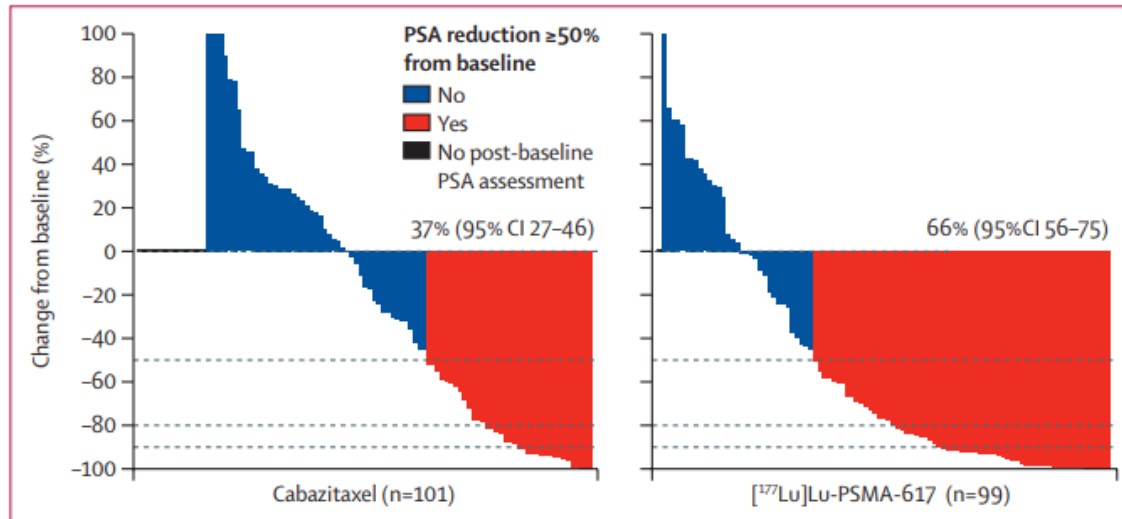
## Centrally read PSMA PET imaging criteria

- PSMA SUV<sub>max</sub>  $\geq$  20 in  $\geq$  1 lesion & SUV<sub>max</sub>  $\geq$  10 in all lesions
- No PSMA-negative FDG-positive metastatic lesions

28% excluded



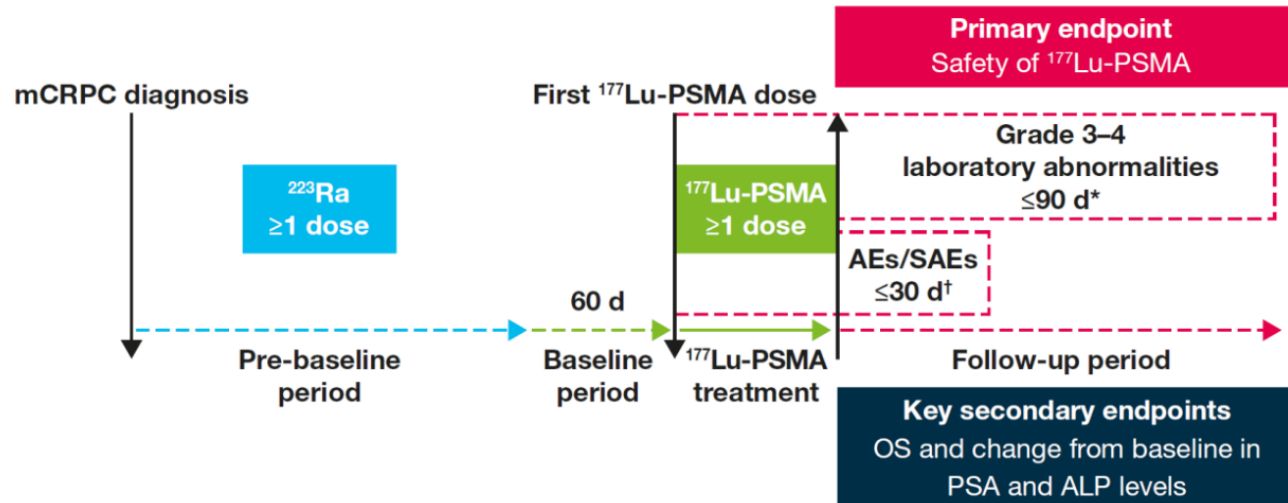
# TheraP: $^{177}\text{Lu}$ -PSMA vs cabazitaxel



Radiographic or PSA PFS

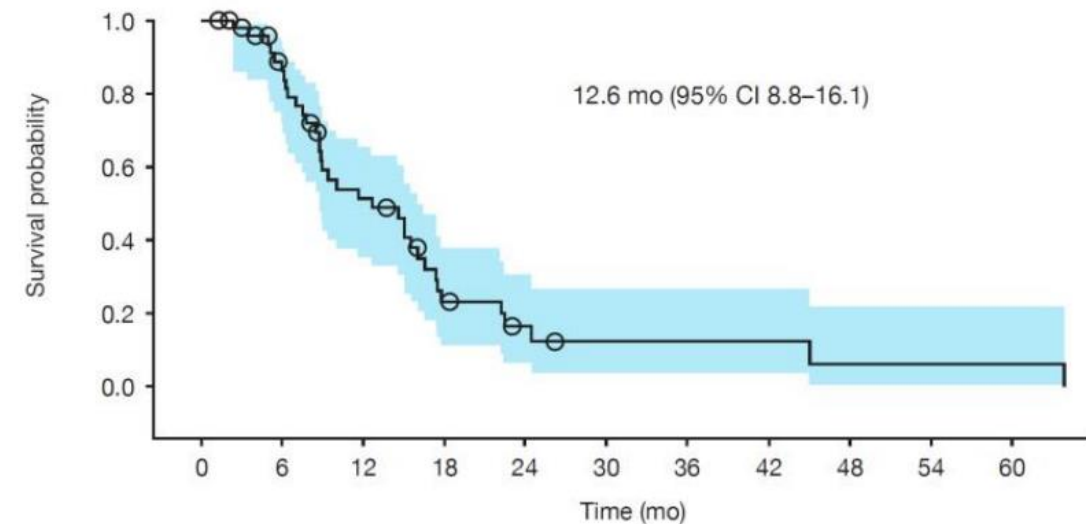
- Overall survival similar: 19.1 months  $^{177}\text{Lu}$ -PSMA vs 19.6 months cabazitaxel
- Lower AE rate with  $^{177}\text{Lu}$ -PSMA

# $^{177}\text{Lu}$ -PSMA after radium?

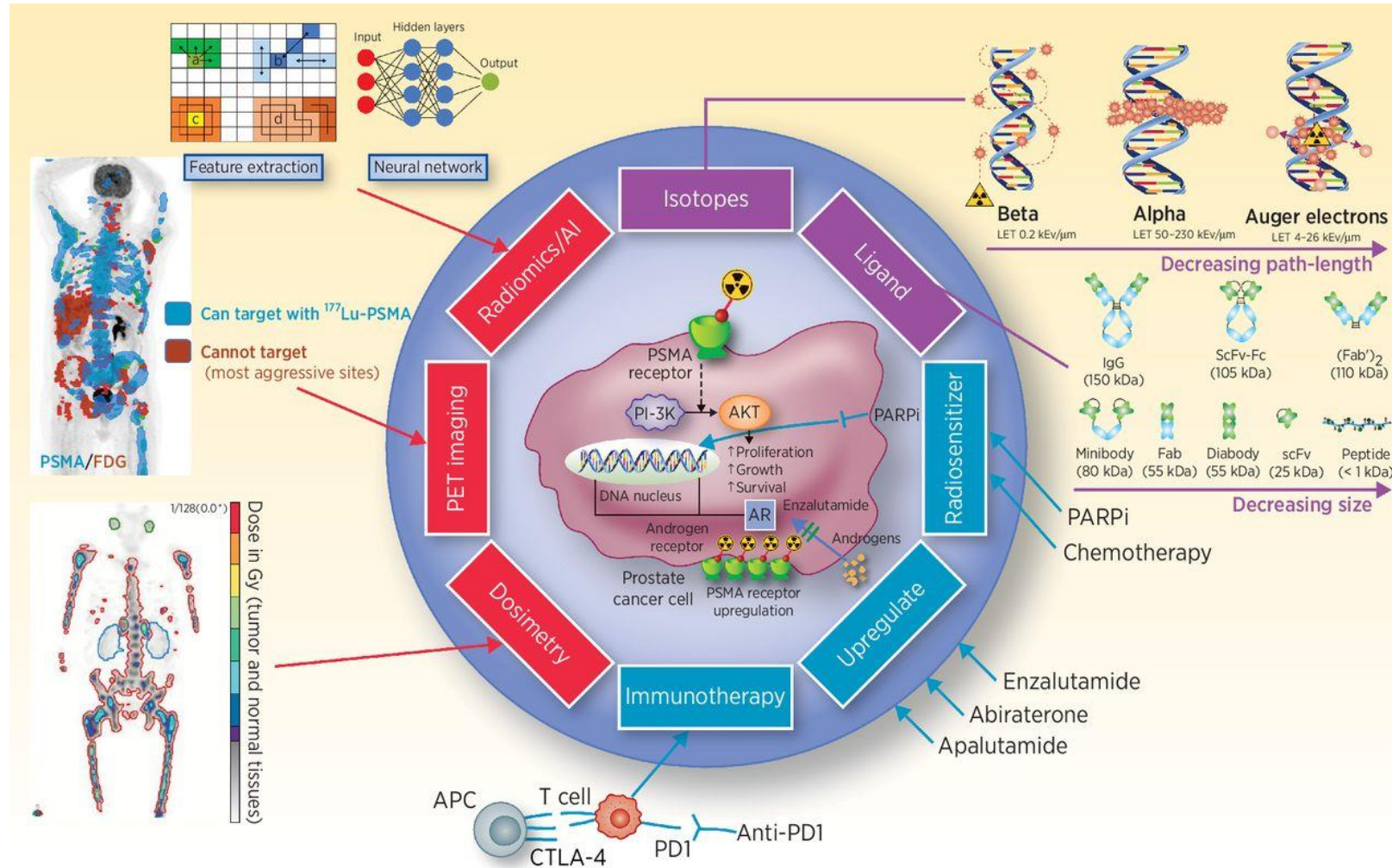


- Retrospective - 49 patients
- 2/3 of patients  $\geq 4$  cycles  $^{177}\text{Lu}$ -PSMA
- Grade 3-4 AEs
  - 30 days: anemia 18% - thrombocytopenia 2%
  - 90 days: anemia 35% - thrombocytopenia 13%
- Acceptable safety profile

**A** From the first  $^{177}\text{Lu}$ -PSMA dose



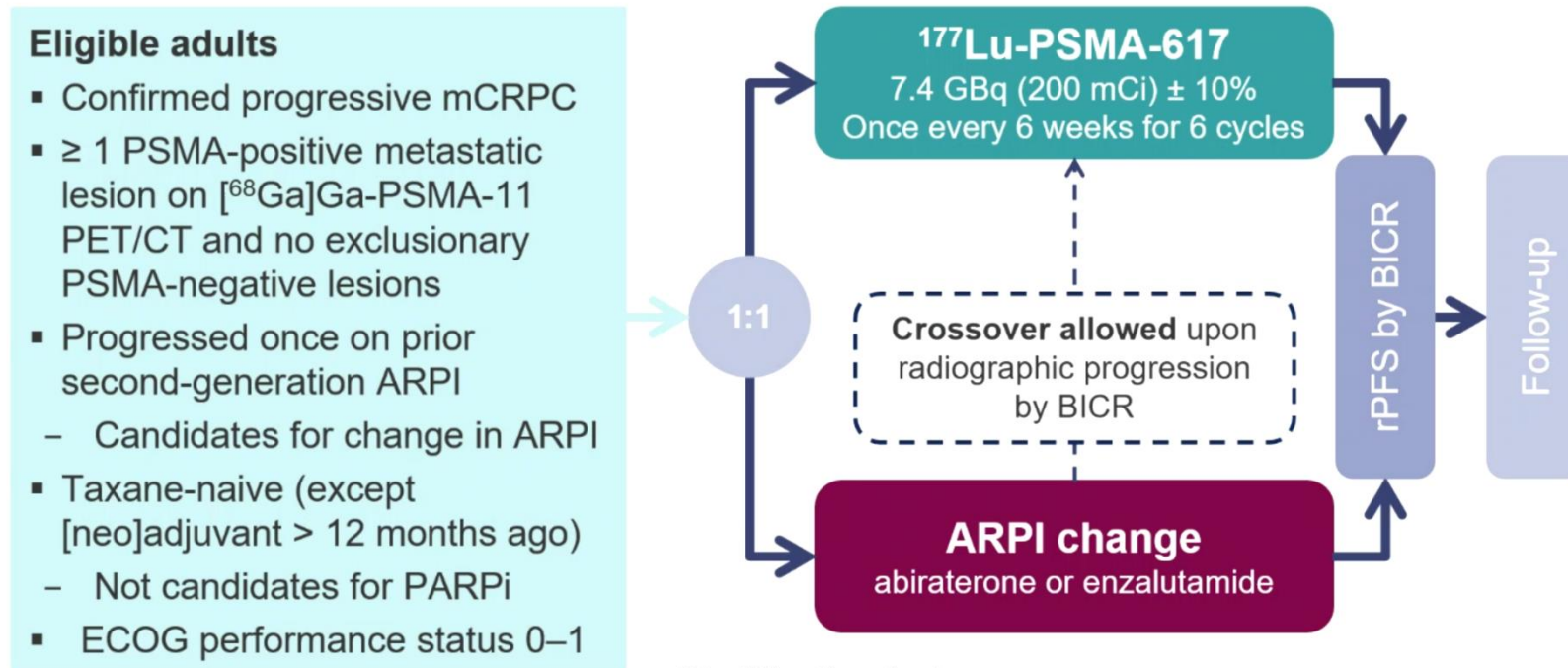
# Future of PSMA-based RLT



# Future of PSMA-based RLT

- Earlier stages of mCRPC or mHSPC
  - Several trials are ongoing (PSMAAddition,...)

## PSMAfore trial (Ph 3)



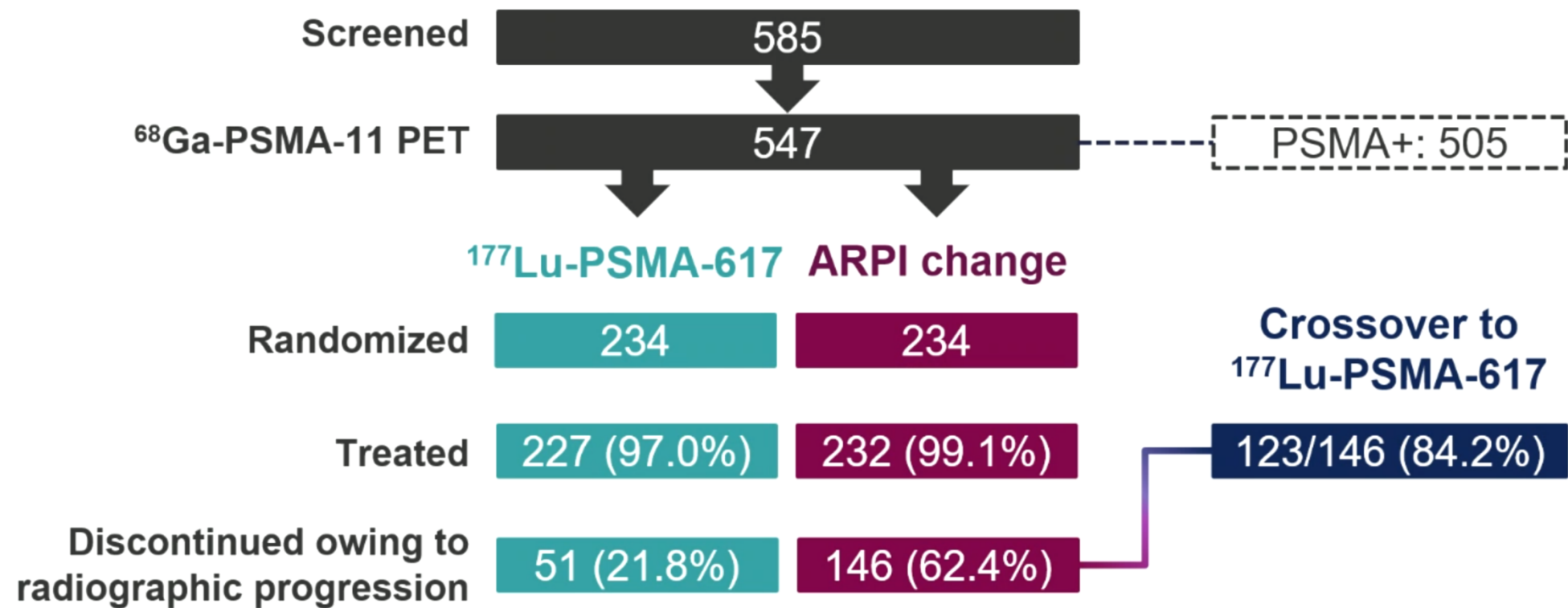
### Stratification factors

- Prior ARPI setting (castration-resistant vs hormone-sensitive)
- BPI-SF worst pain intensity score (0–3 vs > 3)



# Future of PSMA-based RLT - PSMAfore

## Patient disposition at 2nd interim OS analysis

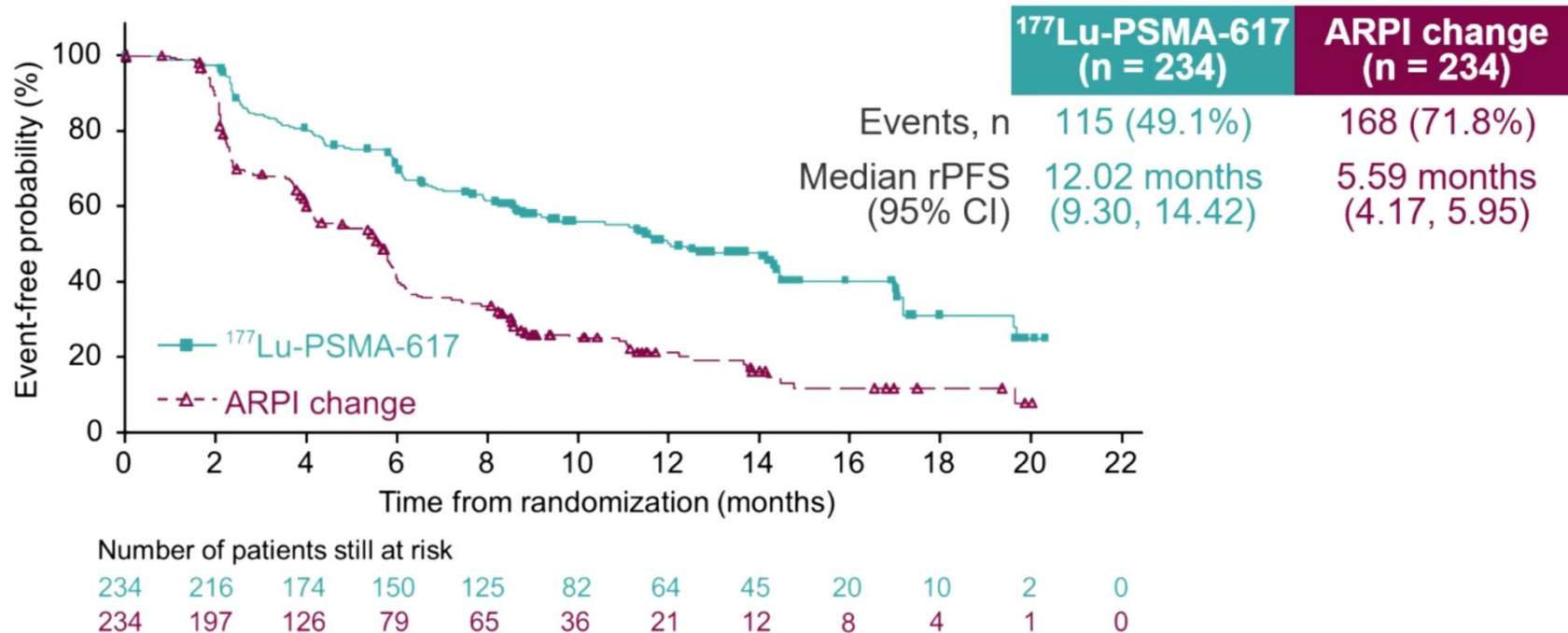


# Future of PSMA-based RLT - PSMAfore

**rPFS: primary endpoint was met**

Primary HR: 0.41 (95% CI: 0.29, 0.56);  $p < 0.0001$

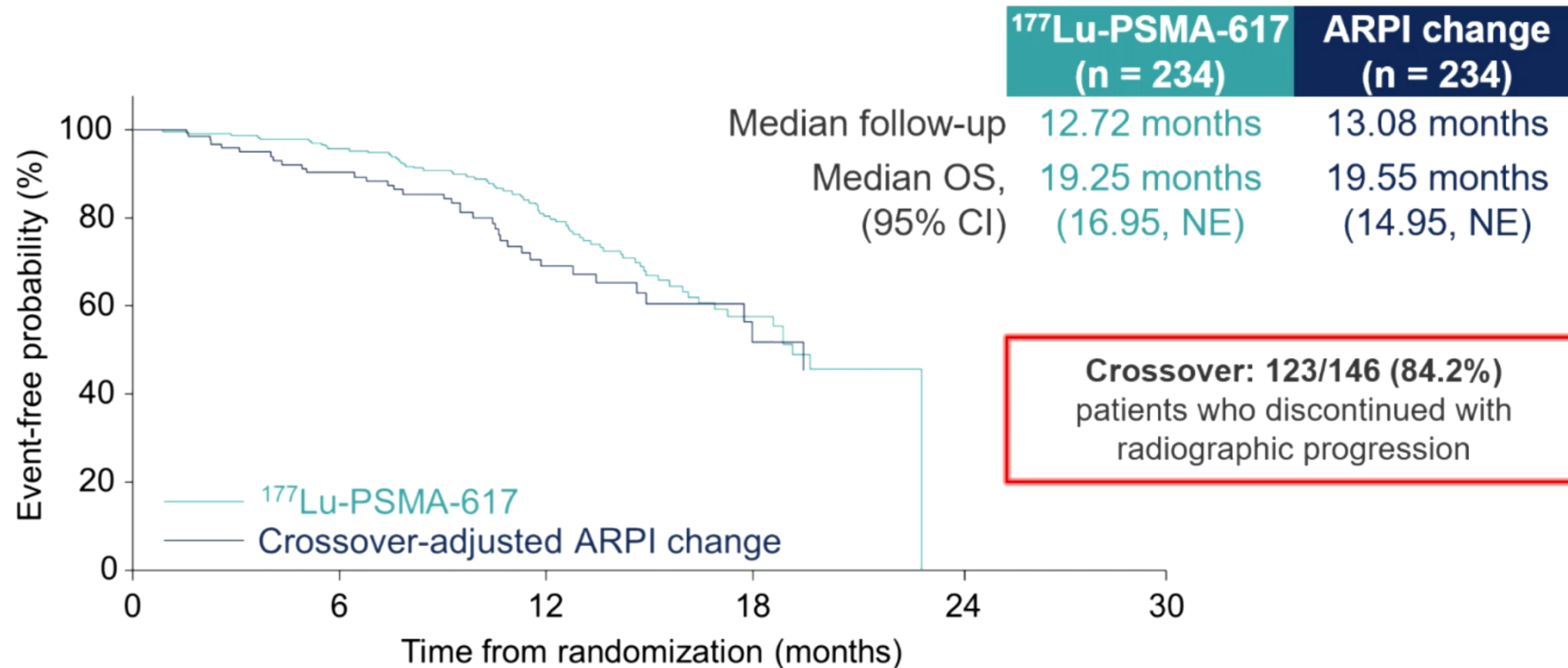
Updated HR: **0.43 (95% CI: 0.33, 0.54)**



# Future of PSMA-based RLT - PSMAfore

## 2nd interim OS: prespecified crossover-adjusted analysis

HR: 0.80 (95% CI: 0.48, 1.33)



# Future of PSMA-based RLT - SPLASH

- Phase 3 trial <sup>177</sup>Lu-PSMA-I&T (<sup>177</sup>Lu-PNT2002) vs ARPI change
  - Patients with PSMA-expressing mCRPC who have progressed on ARPI therapy
  - Refuse, or are not eligible for, chemotherapy
- 412 patients randomized 2:1
  - Crossover from ARPI change arm upon radiographic progression allowed
- Primary endpoint rPFS
  - 9.5 months vs 6.0 months in favor of <sup>177</sup>Lu-PSMA-I&T (HR 0.71, p=0.0088)
  - OS data immature
- Adverse events
  - Favorable safety profile for <sup>177</sup>Lu-PSMA-I&T

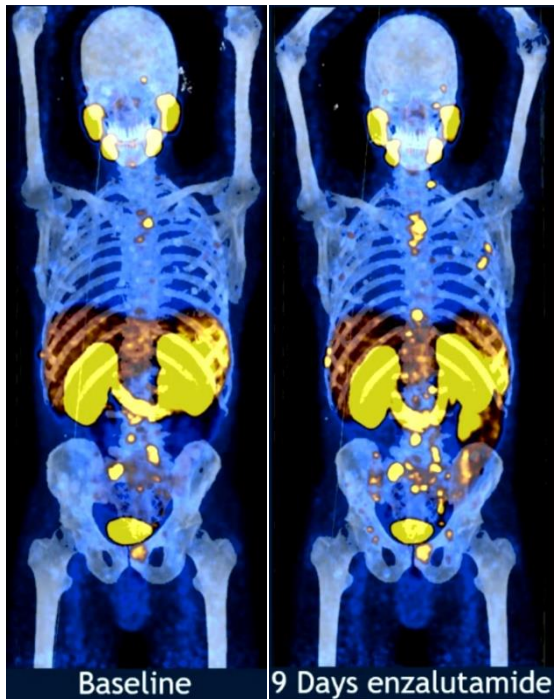
	<sup>177</sup> Lu-PSMA-I&T	ARPI change
Grade ≥3 AEs	30.1%	36.9%
Serious AEs	17.1%	23.1%
AEs to discontinuation	1.9%	6.2%



# Future of PSMA-based RLT - combination

- Combine Lu-PSMA with 'other mode of action' drug
  - Several trials are ongoing

## ENZA-p trial (Ph 2)



### Eligibility

mCRPC with PSA rising and >5ng/mL  
No chemotherapy for mCRPC  
≥2 high risk features for early enzalutamide failure  
Positive <sup>68</sup>Ga PSMA PET/CT

### Stratification

Study Site  
Volume of disease (>20 vs ≤20)  
Early docetaxel for hormone-sensitive disease  
Prior treatment with abiraterone



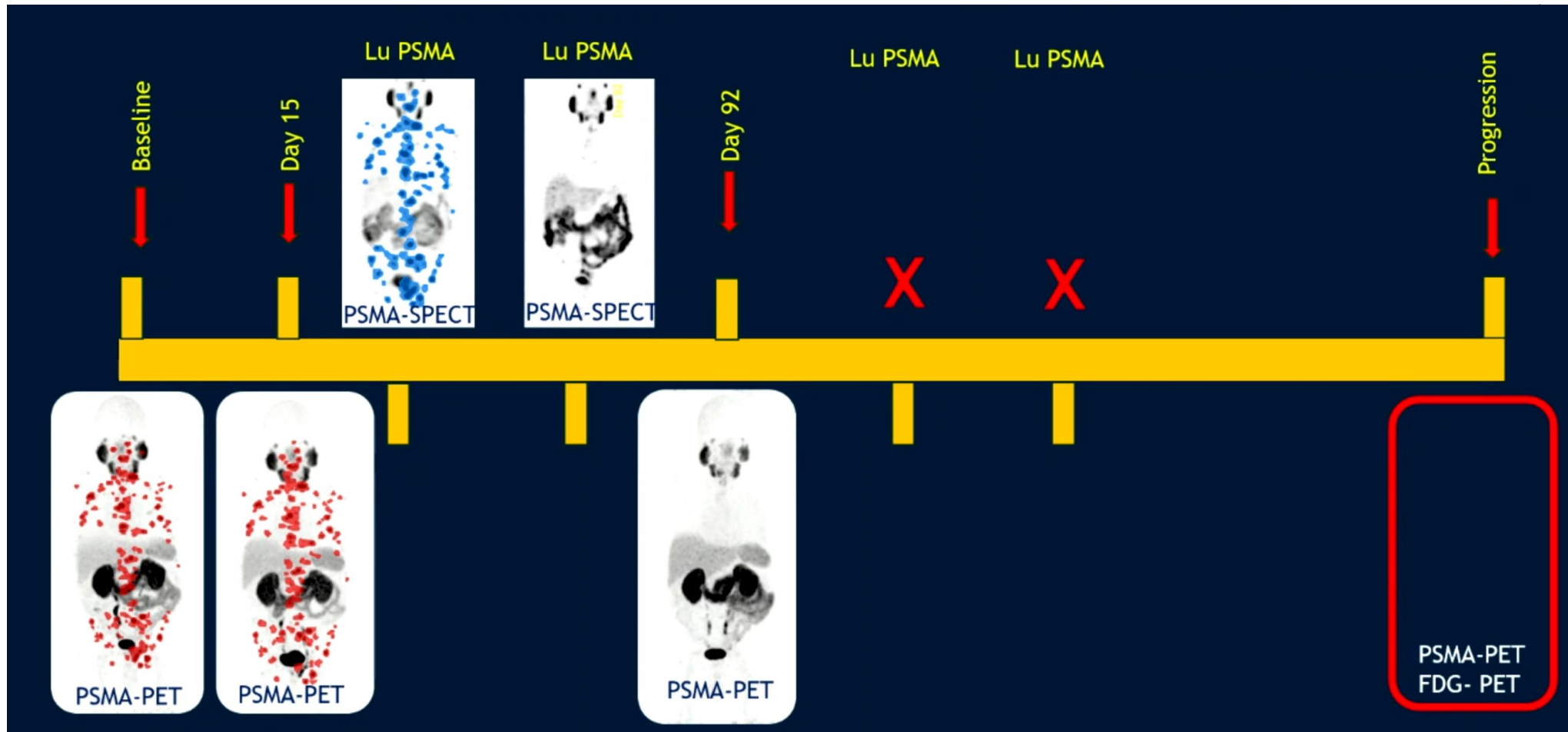
Enzalutamide 160 mg

Enzalutamide 160 mg  
+ Lu-PSMA 7.5 GBq  
2-4 doses

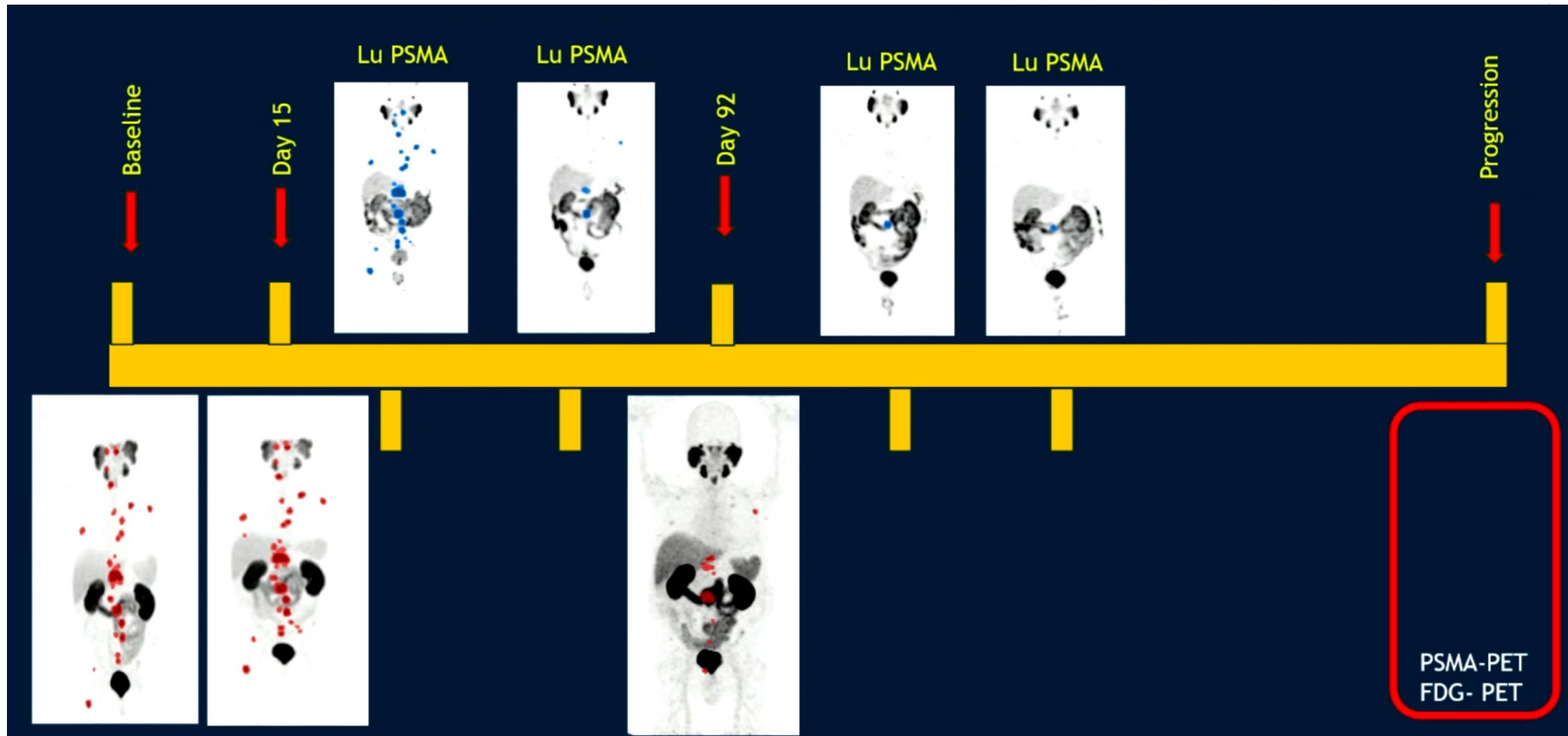
### Objectives

PSA-PFS (primary endpoint)  
Radiographic PFS  
PSA response rate  
Pain response and PFS  
Clinical PFS  
HRQOL  
Adverse events  
Overall survival  
Health economic analyses  
Translational/correlative

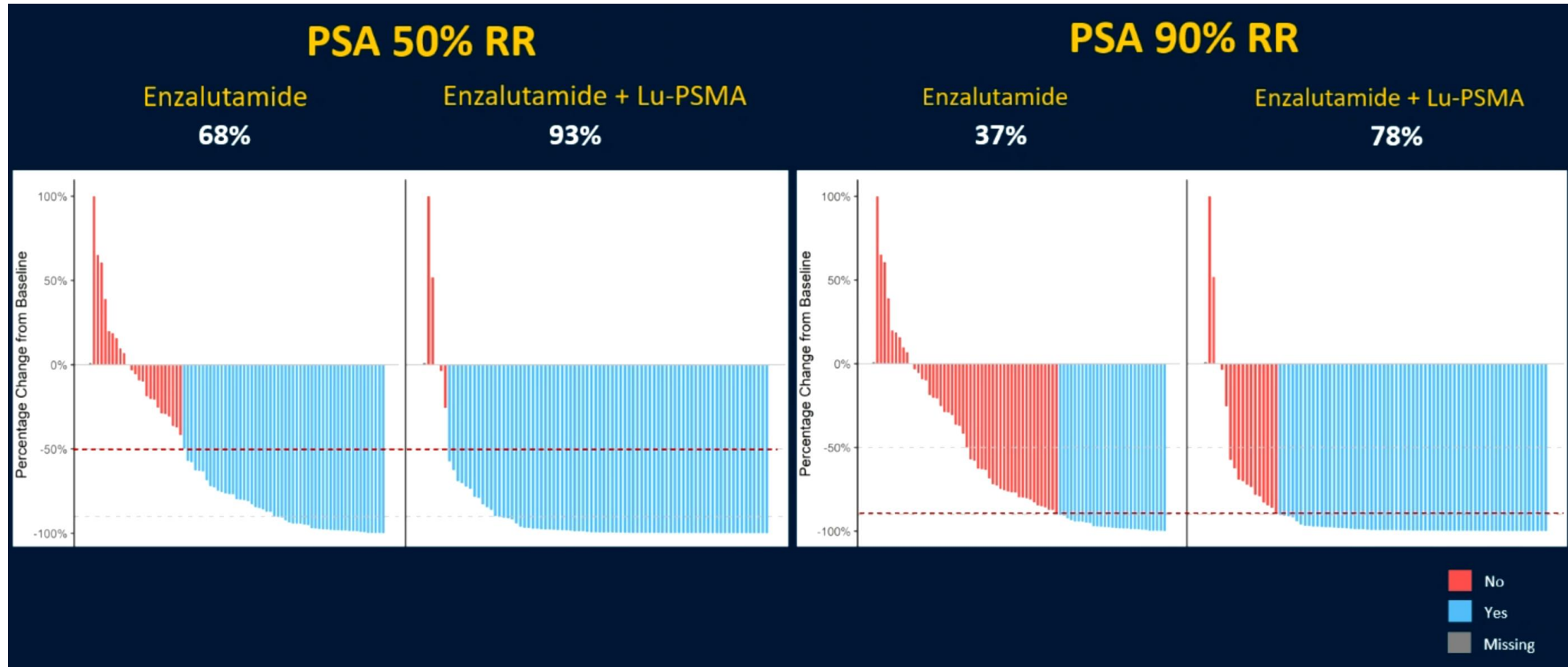
# Future of PSMA-based RLT – adaptive dosing



# Future of PSMA-based RLT – adaptive dosing



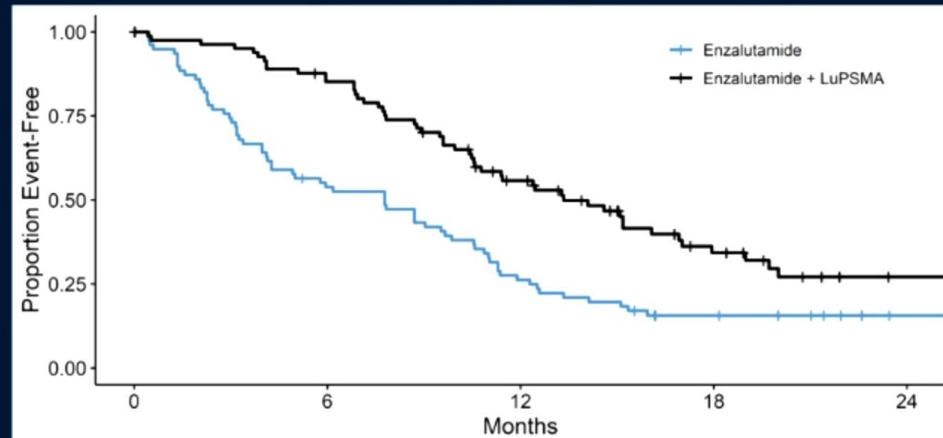
# Future of PSMA-based RLT – ENZA-p



# Future of PSMA-based RLT – ENZA-p

## PSA-PFS

HR 0.43 (95%CI 0.29-0.63) p=0.00001

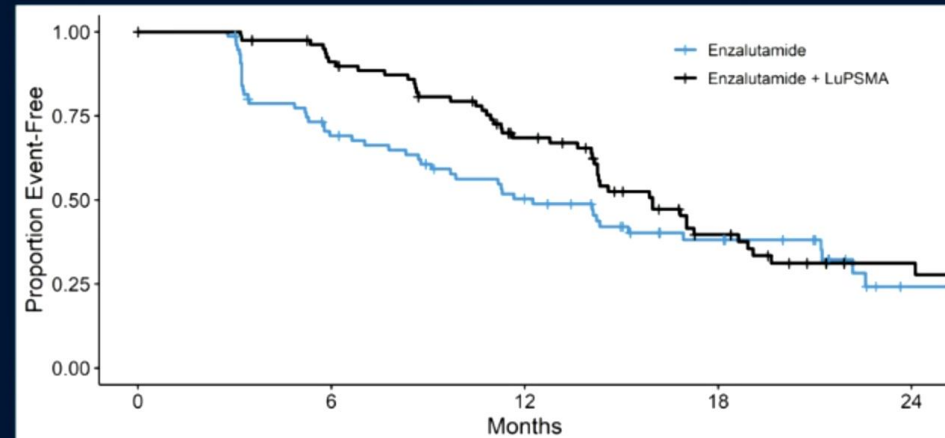


Number at risk (number censored)

Group	0	6	12	18	24
Enzalutamide	79 (0)	41 (2)	20 (2)	9 (5)	2 (12)
Enzalutamide + Lu-PSMA	83 (0)	68 (3)	40 (8)	18 (17)	6 (26)

## R-PFS

HR 0.67 (95% CI 0.44-1.01)



Number at risk (number censored)

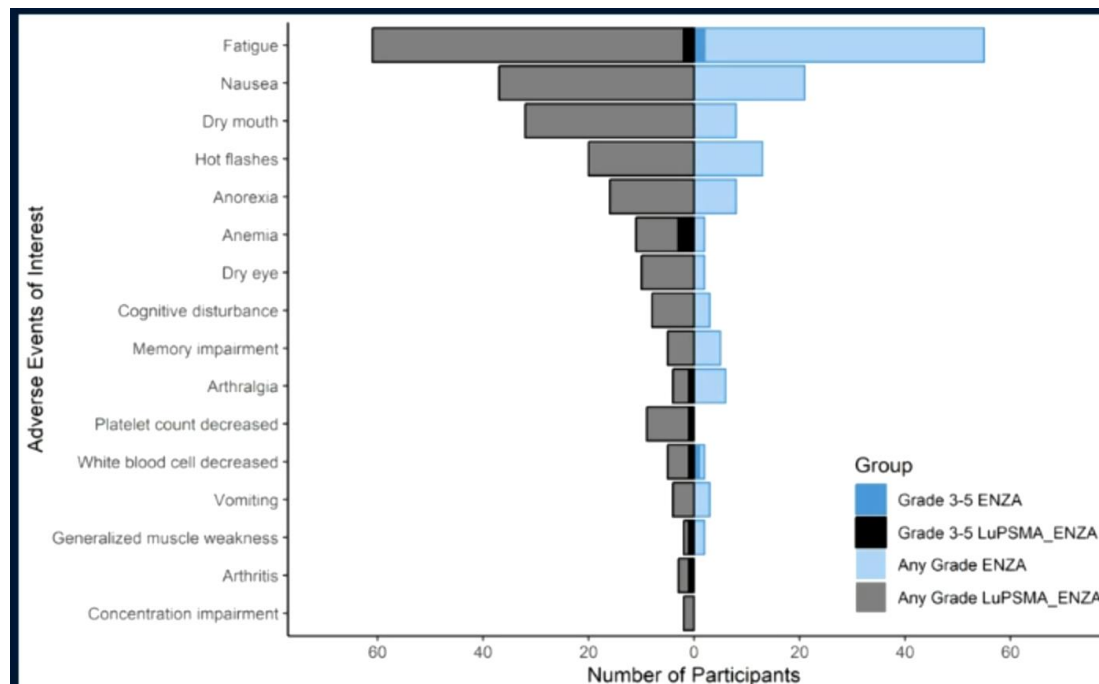
Group	0	6	12	18	24
Enzalutamide	79 (0)	50 (6)	33 (10)	18 (18)	3 (29)
Enzalutamide + Lu-PSMA	83 (0)	71 (5)	47 (12)	20 (22)	9 (29)

PSA-PFS	Participants	Events	Censored	Median Months
Enzalutamide	79	65	14	7.8
Enzalutamide + Lu-PSMA	83	52	31	13

Radiographic-PFS	Participants	Events	Censored	Median Months
Enzalutamide	79	47	35	12
Enzalutamide + Lu-PSMA	83	48	32	16



# Future of PSMA-based RLT – ENZA-p



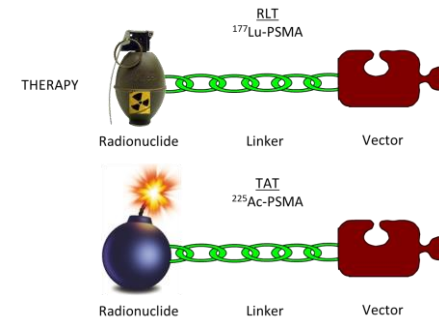
Adverse Event	Enzalutamide n (%)			Enzalutamide + Lu-PSMA n (%)		
	Grade 1-2	Grade 3	Overall	Grade 1-2	Grade 3	Overall
Any AE	64 (81)	3 (4)	67 (85)	69 (85)	8 (10)	77 (95)
Anemia	2 (3)	–	2 (3)	8(10)	3(4)	11(14)
Fatigue	53 (67)	2 (3)	55 (70)	59(73)	2 (2)	61 (75)
Platelets decreased	–	–	–	8(10)	1 (1)	9 (11)
WCC decreased	1(1)	1(1)	2(3)	4(5)	1(1)	4(6)
Arthritis	–	–	–	2(2)	1(1)	3(4)
Dry Mouth	8(10)	–	8(10)	32(40)	–	32 (40)

**Serious adverse events:** Enzalutamide alone 35% (28/79) vs enzalutamide + Lu-PSMA 33% (27/81)

**Grade 4-5 adverse events :**Enzalutamide alone 4% (3/79) vs enzalutamide + Lu-PSMA 6% (8/81)

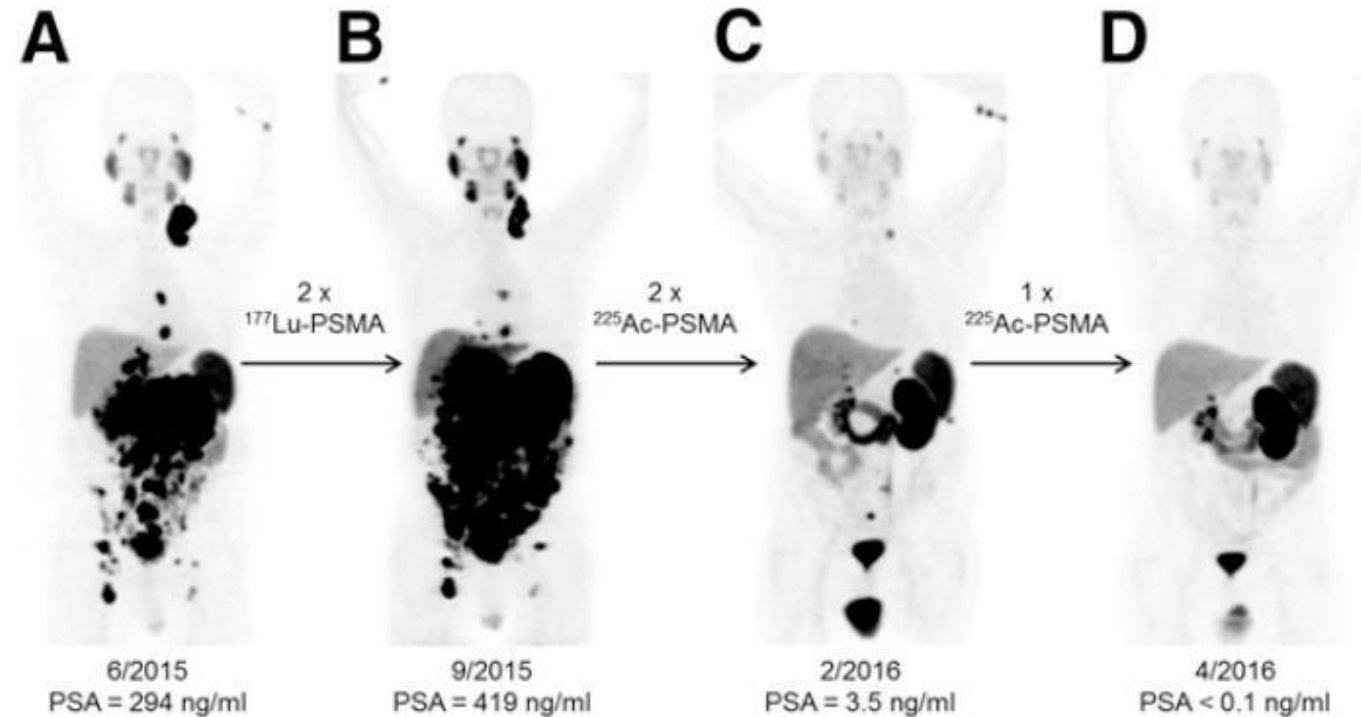
# Beyond beta...

- $^{225}\text{Ac}$  is an  $\alpha$ -emitter like  $^{223}\text{Ra}$  (xogifo)
  - Double strand DNA breaks & short path length => potential OS benefit



Patient B

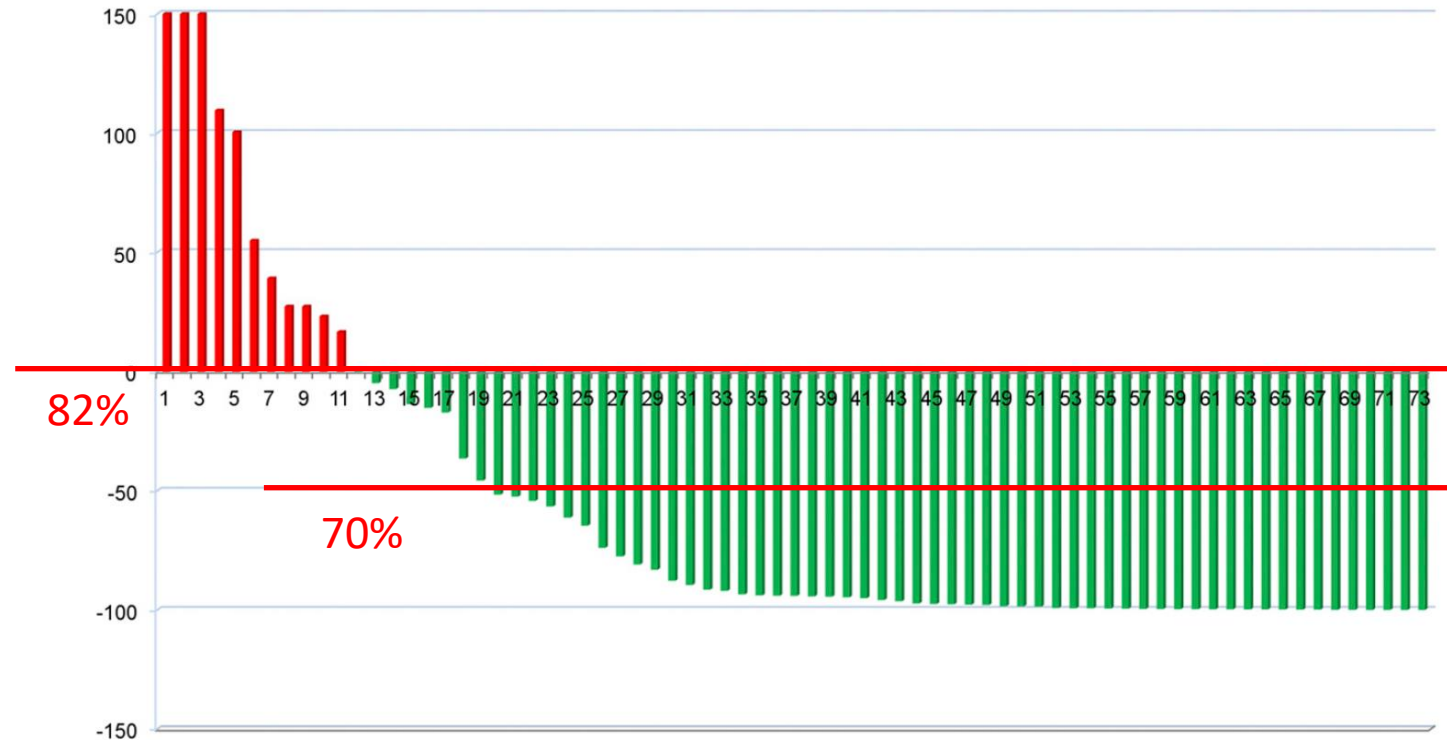
Radical prostatectomy
Radiotherapy of lymph node metastasis
Leuprorelin
Leuprorelin plus bicalutamide, 150 mg/d
Docetaxel (11 cycles)
Cabazitaxel (10 cycles)
Abiraterone
Enzalutamide (not tolerated)



# $^{225}\text{Ac}$ -PSMA RLT - efficacy

Characteristic	Value
No. of patients included	73
Median age (y)	69
≥75 y old	29
ECOG score of 0 or 1	82
ECOG score of ≥2	18
Median PSA level (ng/mL)	57.2
Median alkaline phosphatase level (IU/L)	154
Alkaline phosphatase level of >220 IU/L	27
Median hemoglobin level (g/dL)	11.7
Hemoglobin level of ≤10 g/dL	30
Bone metastases	90
Superscan pattern	38
Visceral metastases	
Lung	3
Liver	5
Brain	1
Local therapy to prostate	
Prostatectomy	33
Radiation therapy	14
No local therapy	53
Therapy for castration-resistant disease	
Chemotherapy	37
Abiraterone	1
Enzalutamide	1
$^{177}\text{Lu}$ -PSMA-617	14
Estimated median OS (mo)	18

73 mCRPC patients





# Sequencing of RNT in mCRPC?

- $^{177}\text{Lu}$ -PSMA RLT
  - VISION: Lu-PSMA vs placebo (post docetaxel)
    - OS benefit, PFS benefit
  - THERA-P: Lu-PSMA vs cabazitaxel (post docetaxel)
    - Response benefit, equal OS
    - Beneficial side-effect profile
  - PSMAfore / SPLASH (mCRPC prior to docetaxel)
    - Response benefit
- $^{225}\text{Ac}$ -PSMA RLT
  - Limited data in end-stage disease
  - Limited supply








# Place of Lu-PSMA in therapeutic spectrum?













Non-metastatic








Metastatic



-  Surveillance
-  Radiotherapy
-  Surgery
-  ADT alone
-  ADT + 1st-gen anti-androgen (recurrence)

-  ADT + docetaxel (CHAARTED, STAMPEDE)
-  ADT + abiraterone + predni (LATITUDE, STAMPEDE)
-  ADT + apalutamide (TITAN)
-  ADT + enzalutamide (ARCHES, ENZAMET)
-  ADT + docetaxel + ARPI (PEACE-1, ARASENS)
-  ADT alone (selected patients: recurrent, low risk old)
-  Radiotherapy: MDT

-  ADT + darolutamide (ARAMIS)
-  ADT + apalutamide (SPARTAN)
-  ADT + enzalutamide (PROSPER)

-  AR pathway inhibitors
-  PARP inhibitors
-  Chemotherapy Docetaxel - Cabazitaxel
-  Radium (ALSYMPCA)
-  <sup>177</sup>Lu-PSMA (VISION)
-  <sup>225</sup>Ac-PSMA
-  Palliative care








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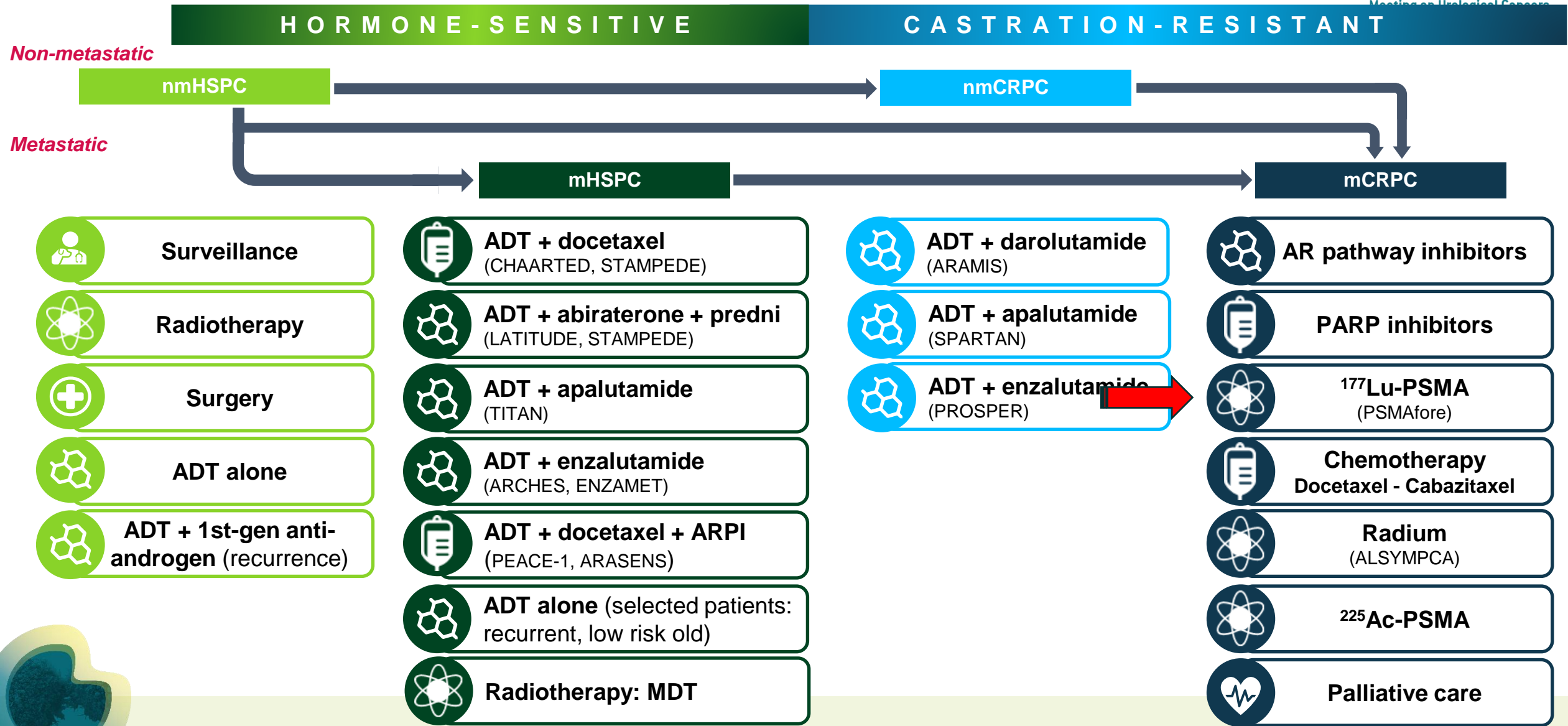
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**11<sup>th</sup> Belgian Multidisciplinary  
Meeting on Urological Cancers**