Innovando en el abordaje multidisciplinar del cáncer de próstata en Andalucía

Málaga, 27 de septiembre de 2023

Organizado por: En colaboración con:

Perfil del paciente candidato a tratamiento con ^{177}Lu-PSMA-617.

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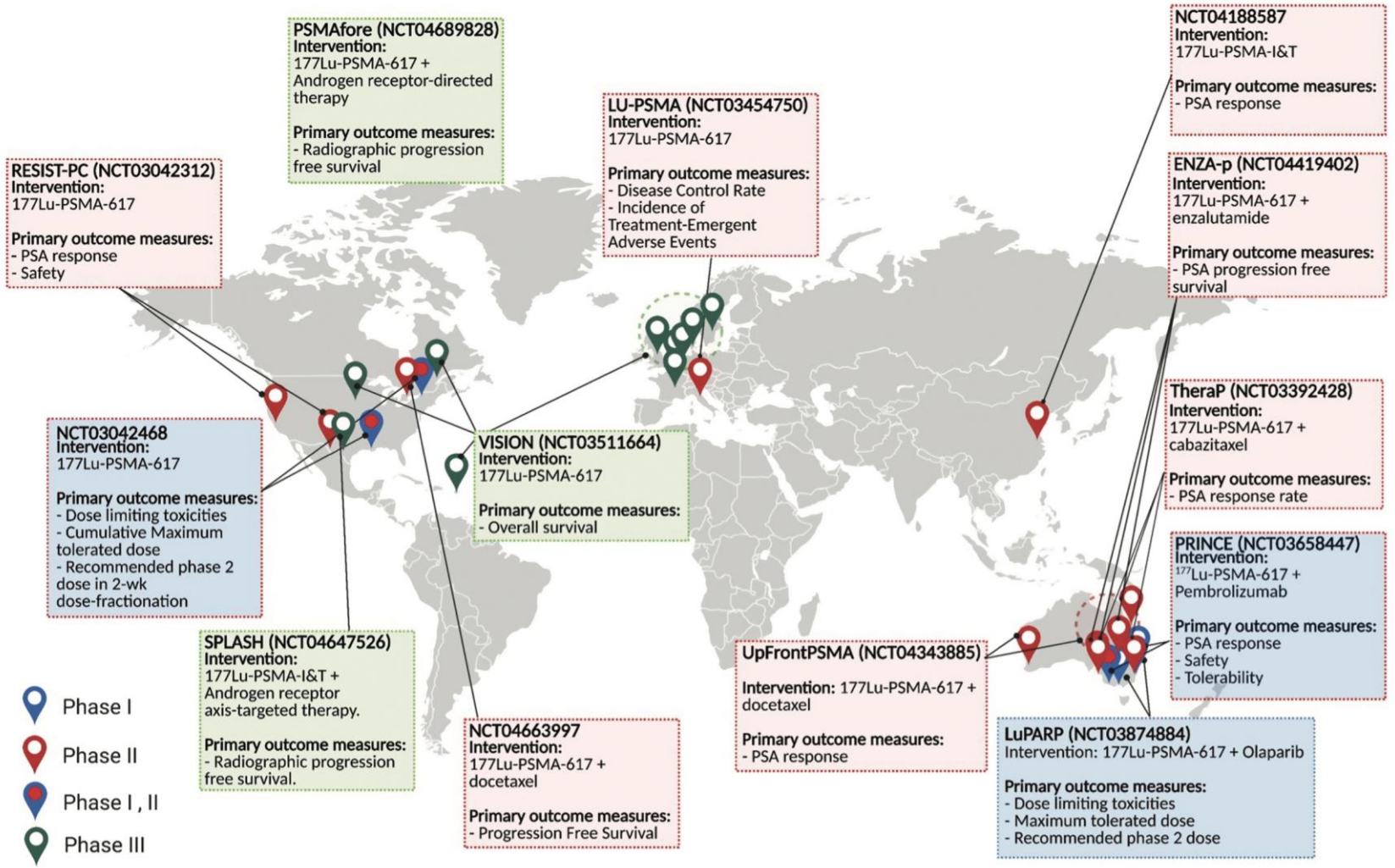
CÁNCER DE PRÓSTATA

CPRCm

- ^{177}Lu-PSMA-617: selección de pacientes

Ensayos clínicos



AlSadi R, et al. Oncologist 2022;27:e957.

PERFIL DE PACIENTE:
Indicación agencias reguladoras

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- ^{177}Lu-PSMA-617

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

AUTHORISED
This medicine is authorised for use in the European Union.

Pluvicto is a medicine used to treat cancer of the prostate (a gland of the male reproductive system). It is used when the cancer is metastatic (spreading to other parts of the body), progressive, castration-resistant (worsens despite treatment to lower levels of the male sex hormone testosterone), and the cancer cells have a protein called prostate-specific membrane antigen (PSMA) on their surface (PSMA-positive prostate cancer).

Pluvicto is used together with androgen deprivation therapy (treatment to lower male sex hormones) in adults previously treated with androgen receptor pathway inhibitors (medicines for prostate cancer), and a medicine of the group of cancer medicines known as taxanes. Androgen receptor pathway inhibitors may also be added to Pluvicto and androgen deprivation therapy.

Pluvicto is a radiopharmaceutical (a medicine that gives off a small amount of radioactivity) that contains the active substance lutetium (^{177}Lu) vipivotide tetraxetan.

Sartor O, et al. N Engl J Med 2021;385(12):1091.

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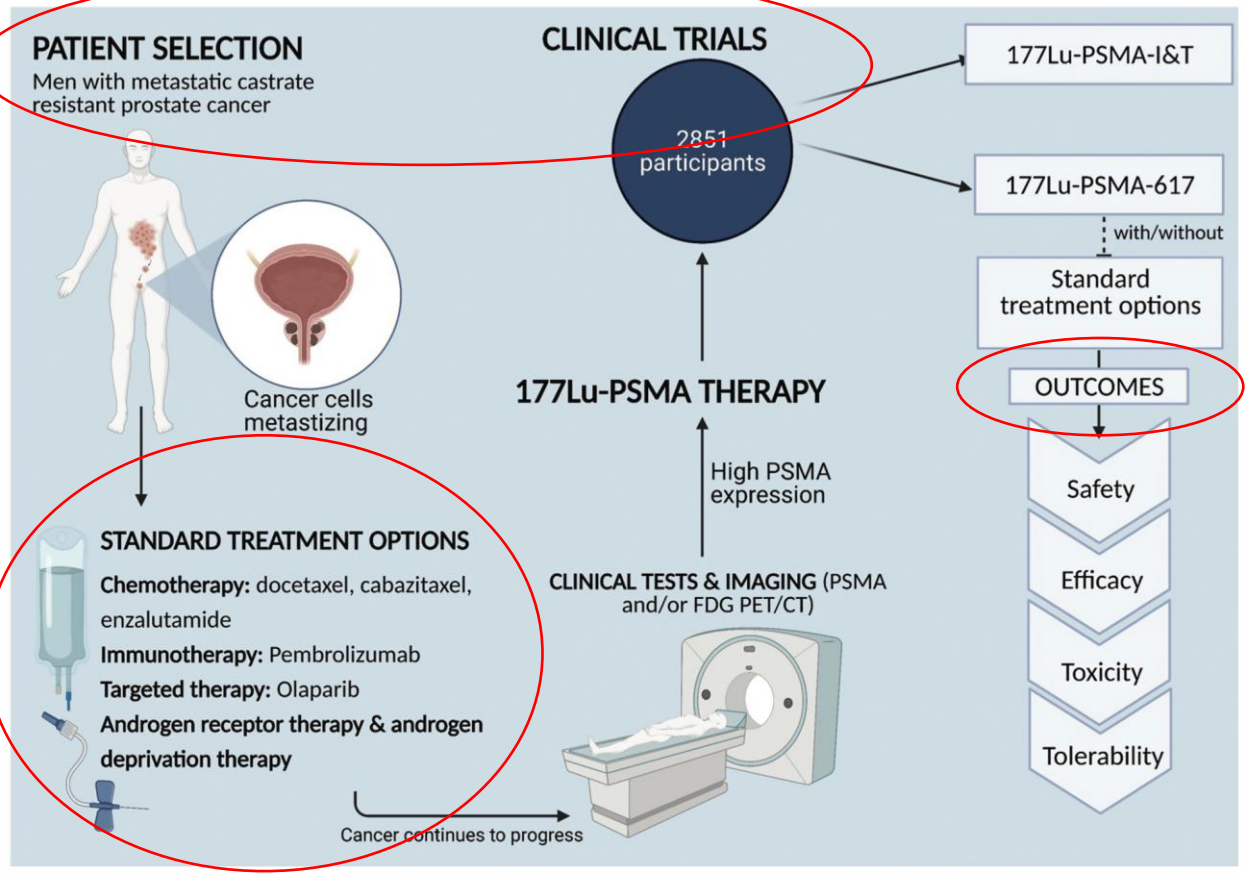

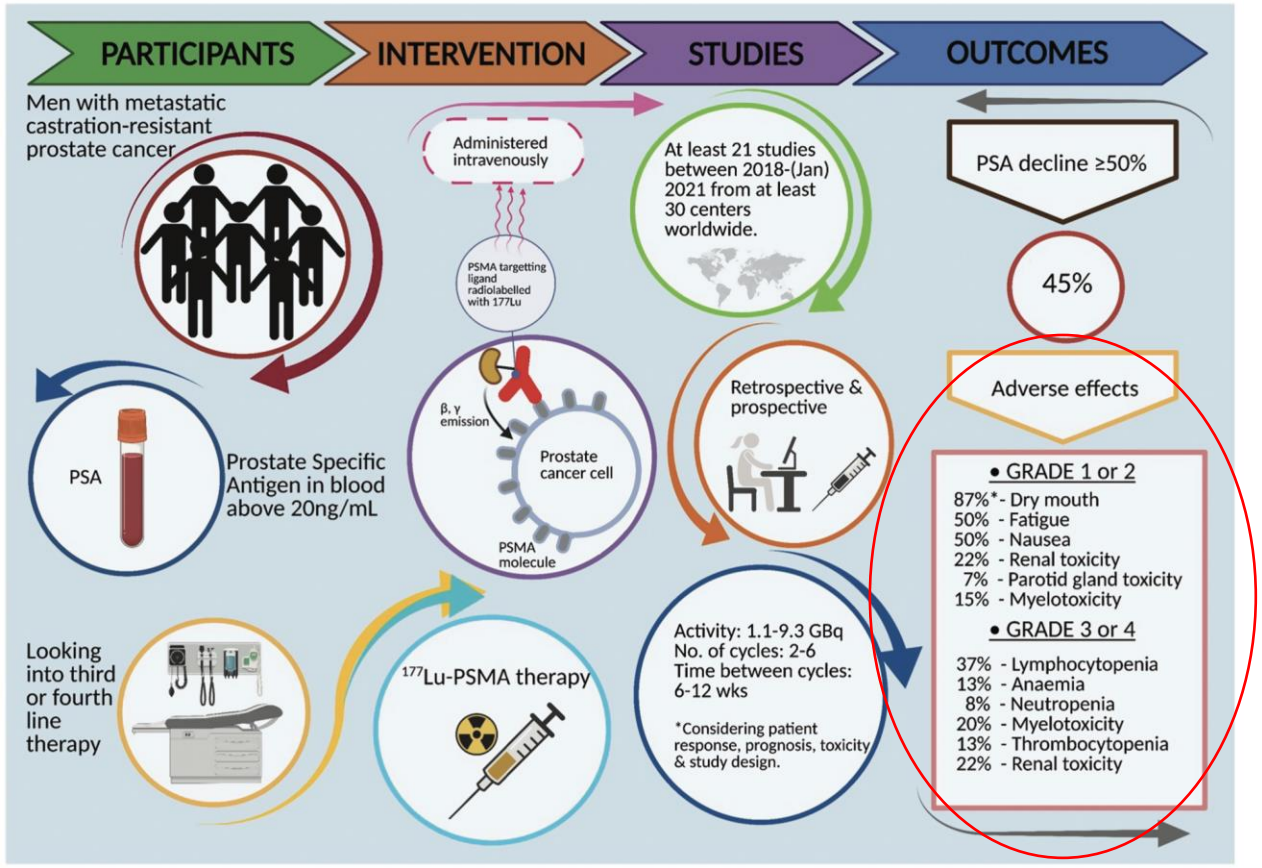

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Innovando en el **abordaje multidisciplinar** del **cáncer de próstata** en Andalucía

Málaga, **27** de **septiembre** de **2023**

Organizado por:

saom Sociedad andaluza de oncología médica

SAMN Sociedad Andaluza de Medicina Nuclear

En colaboración con:

Advanced Accelerator Applications A Novartis Company

PERFIL DE PACIENTE: Criterios de inclusión

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➤ **^{177}Lu-PSMA-617**

VISION

N=831

- **mCRPC post docetaxel**
- **Previous treatment with both:**
  - **≥ 1 ARi**
  - **1 or 2 taxane regimens**
- **Protocol-permitted SOC planned before randomization**
- **Excluding chemo, IO, Ra-223, investigational drugs**
- **ECOG 0-2**
- **PSMA-positive on ^{68}Ga-PSMA-11***

Randomization 2:1

^{177}Lu-PSMA-617 + protocol-permitted SOC
7.4 GBq iv q6 weekly
4 cycles, increasable to 6

Protocol-permitted SOC alone

Approved hormonal treatments
Biphosphonates
Radiation therapy
Denosumab
Glucocorticoids

Primary endpoint: OS
Alternate: rPFS (after March 5, 2019)

Median follow-up -> 20.9 months

Centrally read PSMA PET imaging criteria

- ≥ 1 PSMA-positive metastatic lesion
  - Positive = ^{68}Ga 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

Baseline characteristics

Characteristic	Analysis Set for Imaging-Based Progression-free Survival (N=581)		All Patients Who Underwent Randomization (N=831)	
	^{177}Lu-PSMA-617 plus Standard Care (N=385)	Standard Care Alone (N=196)	^{177}Lu-PSMA-617 plus Standard Care (N=551)	Standard Care Alone (N=280)
Median age (range) — yr	71.0 (52–94)	72.0 (51–89)	70.0 (48–94)	71.5 (40–89)
ECOG performance-status score of 0 or 1 — no. (%)†	352 (91.4)	179 (91.3)	510 (92.6)	258 (92.1)
Site of disease — no. (%)				
Lung	35 (9.1)	20 (10.2)	49 (8.9)	28 (10.0)
Liver	47 (12.2)	26 (13.3)	63 (11.4)	38 (13.6)
Lymph node	193 (50.1)	99 (50.5)	274 (49.7)	141 (50.4)
Bone	351 (91.2)	179 (91.3)	504 (91.5)	256 (91.4)
Median PSA level (range) — ng/ml	93.2 (0–6988)	90.7 (0–6600)	77.5 (0–6988)	74.6 (0–8995)
Median alkaline phosphatase level (range) — IU/liter‡	108.0 (26–2524)	96.0 (34–1355)	105.0 (17–2524)	94.5 (28–1355)
Median LDH (range) — IU/liter‡	230.5 (119–5387)	232.0 (105–2693)	221.0 (88–5387)	224.0 (105–2693)
Median time since diagnosis (range) — yr	7.3 (0.9–28.9)	7.0 (0.7–26.2)	7.4 (0.9–28.9)	7.4 (0.7–26.2)
Gleason score at diagnosis — no. (%)§				
8–10	226 (58.7)	118 (60.2)	324 (58.8)	170 (60.7)
Unknown	28 (7.3)	19 (9.7)	42 (7.6)	24 (8.6)
Previous prostatectomy — no. (%)¶	159 (41.3)	82 (41.8)	240 (43.6)	130 (46.4)
Previous androgen-receptor–pathway inhibitor — no. (%)‖				
One regimen	213 (55.3)	98 (50.0)	298 (54.1)	128 (45.7)
Two regimens	150 (39.0)	86 (43.9)	213 (38.7)	128 (45.7)
More than two regimens	22 (5.7)	12 (6.1)	40 (7.3)	24 (8.6)
Previous taxane therapy — no. (%)**				
One regimen	207 (53.8)	102 (52.0)	325 (59.0)	156 (55.7)
Two regimens	173 (44.9)	92 (46.9)	220 (39.9)	122 (43.6)
Docetaxel	377 (97.9)	191 (97.4)	534 (96.9)	273 (97.5)
Cabazitaxel	161 (41.8)	84 (42.9)	209 (37.9)	107 (38.2)

Sartor O, et al. N Engl J Med 2021;385(12):1091.

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➤ **^{177}Lu-PSMA-617**

TheraP

N=200

- **mCRPC post docetaxel suitable for cabazitaxel**
- **PD with rising PSA and PSA ≥ 20**
- **ECOG 0-2**
- **Previous ARi therapy allowed**
- **PET eligibility criteria***

Primary endpoint: PSA_{50}-RR

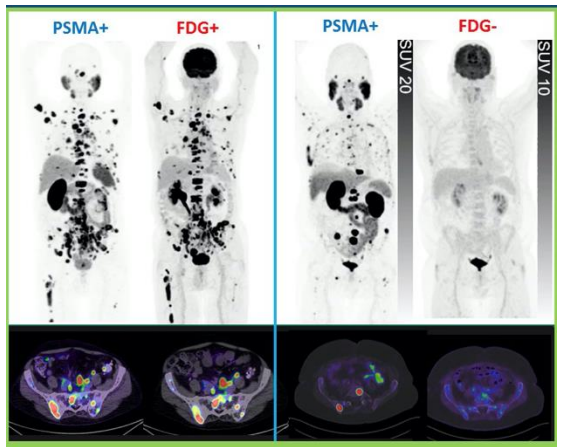
Randomization 1:1

^{177}Lu-PSMA-617
8.5 GBq iv q6 weekly
↓ 0.5 GBq each cycle
Up to 6 cycles

Cabazitaxel
20 mg/m2 iv q3 weekly
Up to 10 cycles

Median follow-up -> 18.4 months

^{68}Ga-PSMA + 18F-FDG PET/CT
- PSMA SUVmax ≥ 20 at any site
- Measurable sites SUVmax > 10
- No FDG positive/PSMA negative sites of disease
- Centrally reviewed



Baseline characteristics

	[^{177}Lu]Lu-PSMA-617 (n=99)	Cabazitaxel (n=101)
Age, years		
Mean (SD)	71·7 (7·9)	71·5 (7·0)
Median (IQR)	72·1 (66·9–76·7)	71·8 (66·7–77·3)
>20 metastases*	77 (78%)	79 (78%)
ECOG performance status		
0	42 (42%)	44 (44%)
1	53 (54%)	52 (52%)
2	4 (4%)	4 (4%)
Missing data	0	1 (1%)
PSA, ng/mL	93·5 (44–219)	110 (64–245)
Alkaline phosphatase, U/L	111 (83–199)	130 (79–187)
Gleason score at diagnosis		
≤7	25 (25%)	35 (35%)
≥8	53 (53%)	50 (50%)
Missing data	21 (21%)	16 (16%)
Disease stage		
Lymph node only	7 (7%)	9 (9%)
Bone metastases	90 (91%)	90 (89%)
Visceral metastases	7 (7%)	13 (13%)
Previous treatment		
Abiraterone only	21 (21%)	24 (24%)
Enzalutamide only	49 (50%)	58 (57%)
Both	21 (21%)	9 (9%)

Hofman MS, et al. Lancet 2021;397:797.

PERFIL DE PACIENTE: Factores predictores

CÁNCER DE PRÓSTATA

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➤ ^{177}Lu-PSMA-617: subgrupos

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Radiation therapy
Denosumab
Glucocorticoids

Primary endpoint: OS
Alternate: rPFS (after March 5, 2019)

Median follow-up -> 20.9 months

Centrally read PSMA PET imaging criteria

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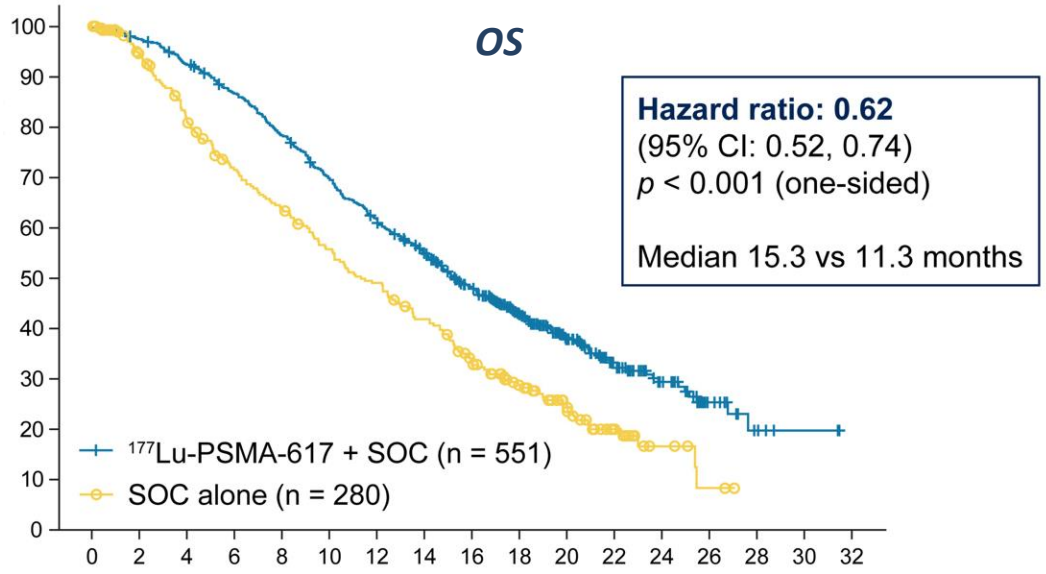
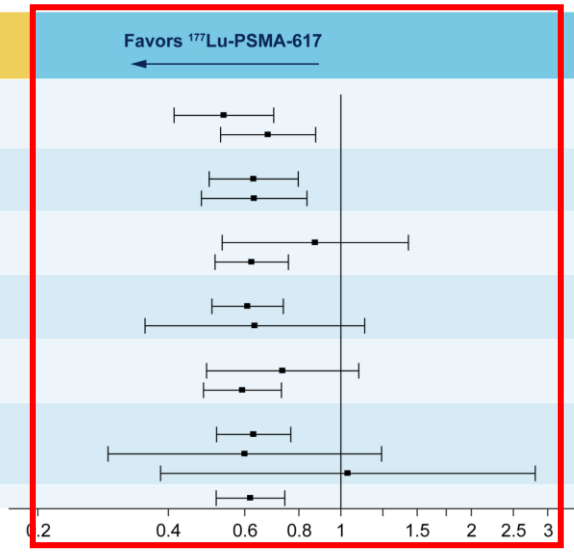


OS by subgroups

Subgroup	^{177}Lu-PSMA-617 + SOC (n = 551)	SOC alone (n = 280)	Hazard ratio (95% CI)
Androgen receptor pathway inhibitors as part of planned SOC			
Yes	243	146	0.54 (0.41, 0.70)
No	308	134	0.68 (0.53, 0.87)
LDH			
≤ 260 IU/L	368	182	0.63 (0.50, 0.80)
> 260 IU/L	182	97	0.63 (0.48, 0.84)
Liver metastases			
Yes	48	34	0.87 (0.53, 1.43)
No	503	246	0.62 (0.51, 0.76)
ECOG score			
0 or 1	510	258	0.61 (0.50, 0.74)
2	41	22	0.63 (0.35, 1.13)
Age			
< 65 years	145	60	0.73 (0.49, 1.10)
≥ 65 years	406	220	0.59 (0.48, 0.73)
Race			
White	486	235	0.63 (0.52, 0.77)
African American or Black	34	21	0.60 (0.29, 1.24)
Asian	9	11	1.04 (0.38, 2.81)
All patients	551	280	0.62 (0.52, 0.74)



De Bono J, et al. J Clin Oncol 2021;39(suppl 15;LBA4).

CÁNCER DE PRÓSTATA

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➤ ^{177}Lu-PSMA-617: subgrupos

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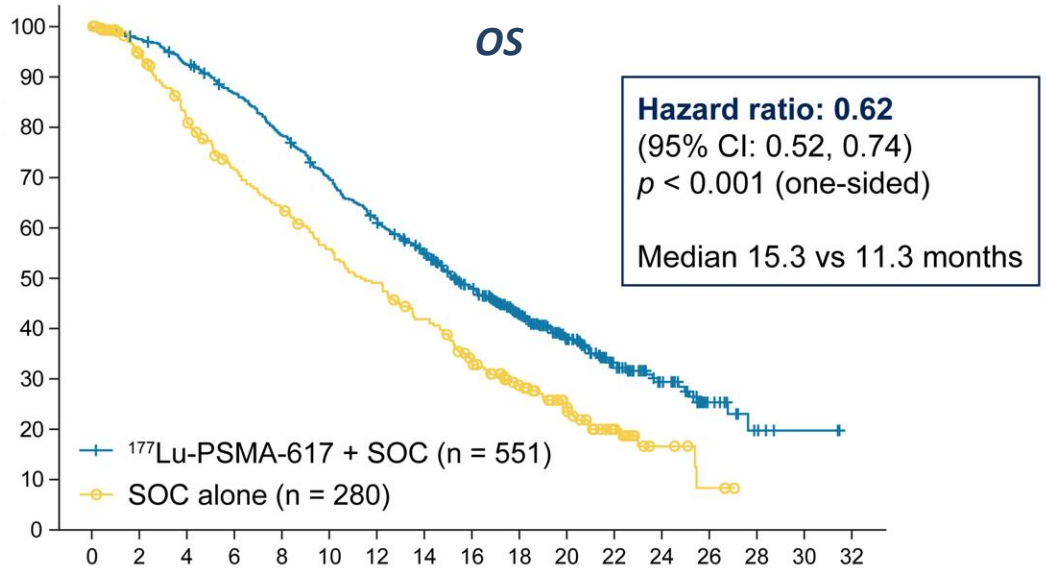

OS by prior treatments

		^{177}Lu-PSMA-617 + SoC (n = 551) n/N (%)	SoC alone (n = 280) n/N (%)	HR (95% CI)
ARPIs	1	182/296 (61.5)	83/130 (63.8)	0.74 (0.57, 0.97)
	≥ 2	161/255 (63.1)	104/150 (69.3)	0.52 (0.41, 0.67)
Taxane regimens	1	206/342 (60.2)	108/165 (65.5)	0.59 (0.46, 0.75)
	≥ 2	113/170 (66.5)	70/99 (70.7)	0.73 (0.53, 0.99)
Non-taxane regimens	0	299/485 (61.6)	167/252 (66.3)	0.61 (0.50, 0.74)
	≥ 1	44/66 (66.7)	20/28 (71.4)	0.71 (0.42, 1.23)
Immunotherapies	0	255/414 (61.6)	134/200 (67.0)	0.58 (0.47, 0.73)
	≥ 1	88/137 (64.2)	53/80 (66.3)	0.72 (0.51, 1.01)
Bone health agents	Yes	66/99 (66.7)	43/57 (75.4)	0.54 (0.36, 0.80)
	No	277/452 (61.3)	144/223 (64.6)	0.64 (0.52, 0.79)
^{223}Ra	Yes	59/97 (60.8)	31/48 (64.6)	0.73 (0.47, 1.13)
	No	284/454 (62.6)	156/232 (67.2)	0.60 (0.49, 0.73)
PARP inhibitors	Yes	22/30 (73.3)	11/16 (68.8)	0.60 (0.28, 1.28)
	No	321/521 (61.6)	176/264 (66.7)	0.62 (0.51, 0.75)
All patients		**343/551 (62.3)**	**187/280 (66.8)**	**0.62 (0.52, 0.74)**

Favors ^{177}Lu-PSMA-617 — Favors SoC

0.05 0.2 0.8 3.2

Vaishampayan N, et al. J Clin Oncol 2022;40(suppl 16;abstr 5001).

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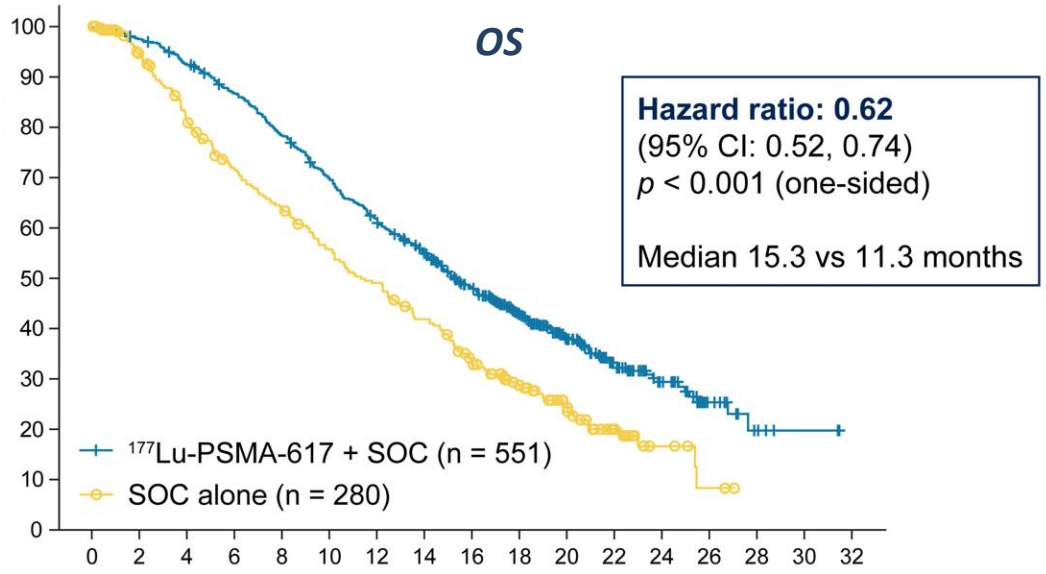
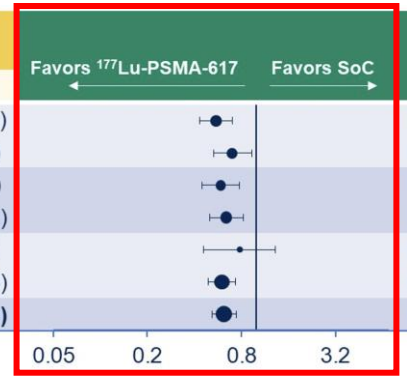


OS by concomitant SoC treatment

		^{177}Lu-PSMA-617 + SoC (n = 551) n/N (%)	SoC alone (n = 280) n/N (%)	HR (95% CI)
ARPIs	Yes	166/289 (57.4)	110/166 (66.3)	0.55 (0.43, 0.70)
	No	177/262 (67.6)	77/114 (67.5)	0.70 (0.53, 0.93)
Bone health agents	Yes	152/240 (63.3)	86/125 (68.8)	0.59 (0.45, 0.78)
	No	191/311 (61.4)	101/155 (65.2)	0.64 (0.50, 0.82)
Radiation therapy	Yes	51/75 (68.0)	22/31 (71.0)	0.78 (0.46, 1.32)
	No	292/476 (61.3)	165/249 (66.3)	0.60 (0.49, 0.73)
All patients		**343/551 (62.3)**	**187/280 (66.8)**	**0.62 (0.52, 0.74)**



Vaishampayan N, et al. J Clin Oncol 2022;40(suppl 16;abstr 5001).

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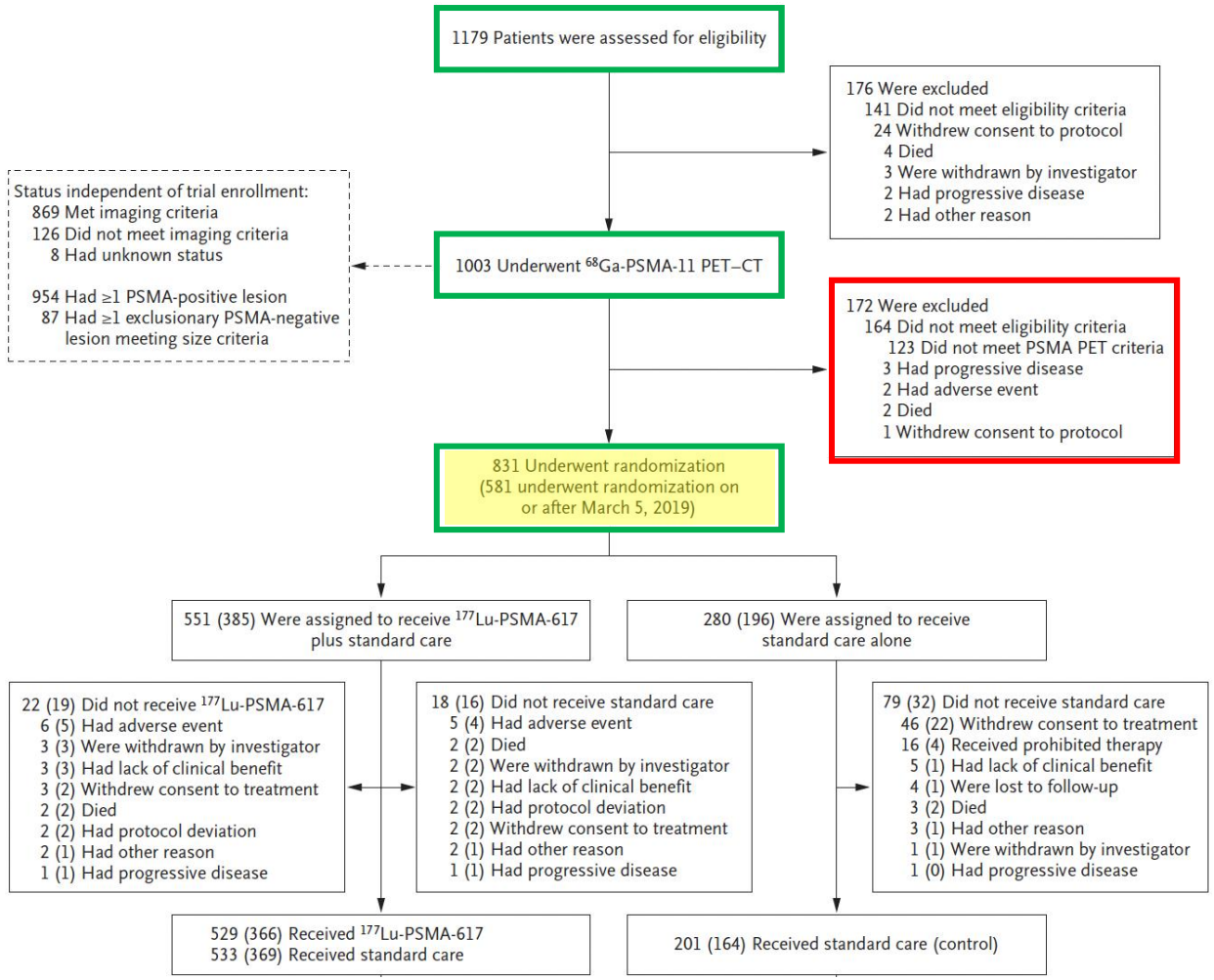
Screening and randomization



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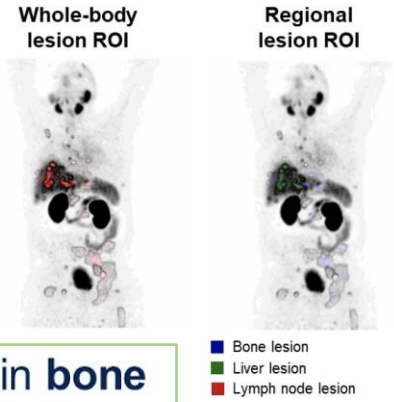
Objective: to assess the association between quantitative parameters from pre-treatment ^{68}Ga-PSMA-11 PET/CT scans and outcomes (rPFS, OS, ORR and PSA response[a]) with ^{177}Lu-PSMA-617 therapy

PSMA PET parameters
- SUV_{mean}
- SUV_{max}
- Tumor volume
- Tumor load
- Presence of PSMA-positive lesion by region (Yes/No)

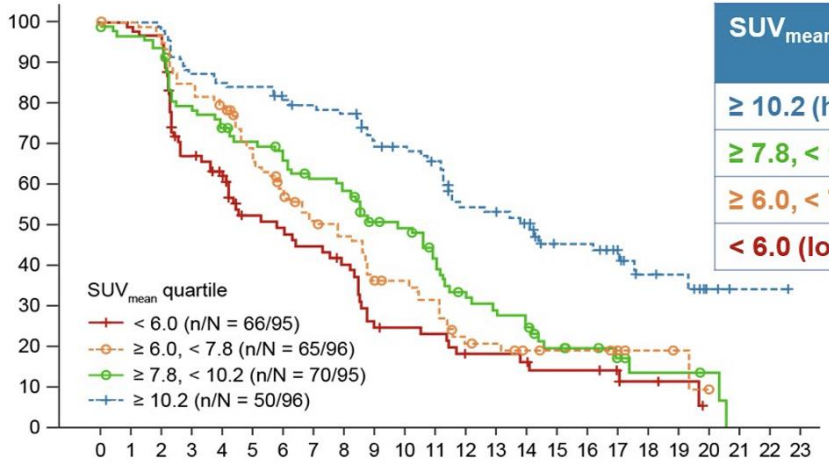
Extracted for

Segmented anatomical regions
- Bone
- Lymph node
- Liver
- Other soft tissue
- Whole body (combination of all regions)



- **92.7%** had positive ^{68}Ga-PSMA-11 uptake in **bone**
- **13.1%** had positive ^{68}Ga-PSMA-11 uptake in **liver**

Higher whole-body SUV_{mean} was associated with prolonged rPFS



SUV_{mean} quartile	Median rPFS (months)
≥ 10.2 (highest)	14.1
≥ 7.8, < 10.2	9.8
≥ 6.0, < 7.8	7.8
< 6.0 (lowest)	5.8

Armstrong AJ, et al. J Clin Oncol 2022;40(suppl 16;abstr 5002).

CÁNCER DE PRÓSTATA

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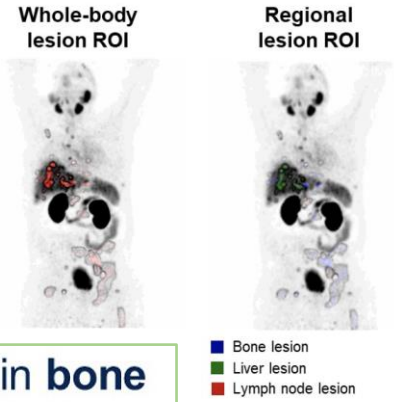
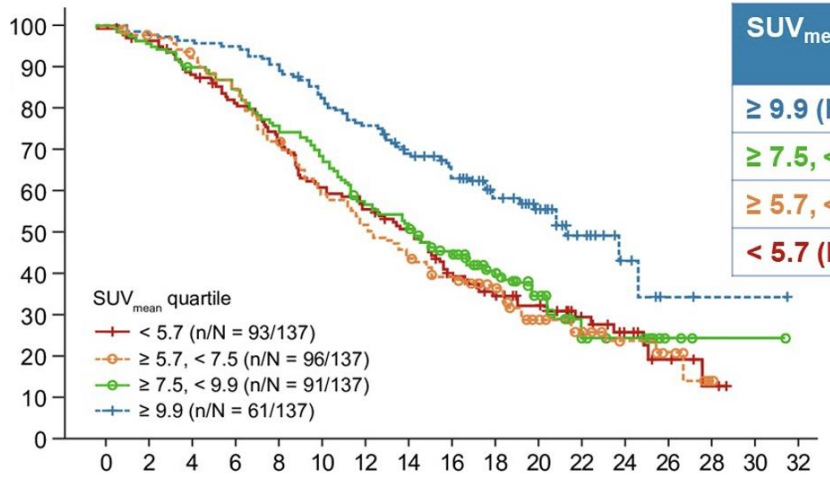
- Other soft tissue
- Whole body (combination of all regions)



- **92.7%** had positive ^{68}Ga-PSMA-11 uptake in **bone**
- **13.1%** had positive ^{68}Ga-PSMA-11 uptake in **liver**

Higher whole-body SUV_{mean} was associated with improved OS



SUV_{mean} quartile	Median OS (months)
≥ 9.9 (highest)	21.4
≥ 7.5, < 9.9	14.6
≥ 5.7, < 7.5	12.6
< 5.7 (lowest)	14.5

Armstrong AJ, et al. J Clin Oncol 2022;40(suppl 16;abstr 5002).

CÁNCER DE PRÓSTATA

CPRCm

➤ **^{177}Lu-PSMA-617: factores predictores**

VISION

N=831

- **mCRPC post docetaxel**
- **Previous treatment with both:**
  - **≥ 1 ARi**
  - **1 or 2 taxane regimens**
- **Protocol-permitted SOC planned before randomization**
- **Excluding chemo, IO, Ra-223, investigational drugs**
- **ECOG 0-2**
- **PSMA-positive on ^{68}Ga-PSMA-11***

Randomization 2:1

^{177}Lu-PSMA-617 + protocol-permitted SOC
7.4 GBq iv q6 weekly
4 cycles, increasable to 6

Protocol-permitted SOC alone

Approved hormonal treatments
Biphosphonates
Radiation therapy
Denosumab
Glucocorticoids

Primary endpoint: OS
Alternate: rPFS (after March 5, 2019)

Median follow-up -> 20.9 months

Centrally read PSMA PET imaging criteria

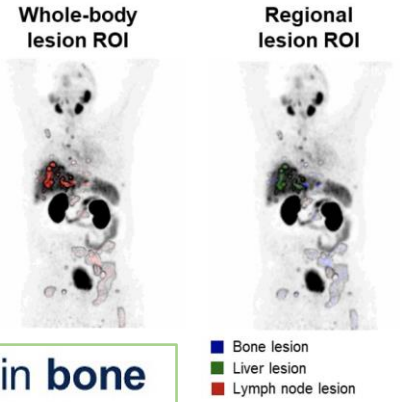
- ≥ 1 PSMA-positive metastatic lesion
  - Positive = ^{68}Ga uptake > liver
- No PSMA-negative metastatic lesions
  - Bone with soft tissue component ≥ 1.0 cm
  - Lymph node ≥ 2.5 cm
  - Solid organ ≥ 1.0 cm

Objective: to assess the association between quantitative parameters from pre-treatment ^{68}Ga-PSMA-11 PET/CT scans and outcomes (rPFS, OS, ORR and PSA response[a]) with ^{177}Lu-PSMA-617 therapy

PSMA PET parameters
- SUV_{mean}
- SUV_{max}
- Tumor volume
- Tumor load
- Presence of PSMA-positive lesion by region (Yes/No)

Extracted for

Segmented anatomical regions
- Bone
- Lymph node
- Liver
- Other soft tissue
- Whole body (combination of all regions)



– **92.7%** had positive ^{68}Ga-PSMA-11 uptake in **bone**
– **13.1%** had positive ^{68}Ga-PSMA-11 uptake in **liver**

Anatomical region	rPFS HR [95% CI], *p* value	OS HR [95% CI], *p* value	ORR OR [95% CI], *p* value	PSA50 OR [95% CI], *p* value
Bone	0.45 [0.26, 0.78], 0.004	0.38 [0.22, 0.67], < 0.001	3.06 [1.12, 8.38], 0.03	NS
Liver	0.48 [0.34, 0.67], < 0.001	0.49 [0.37, 0.66], < 0.001	2.55 [1.02, 6.34], 0.045	2.42 [1.21, 4.86], 0.013

Absence of PSMA+ lesions in bone and liver associated with a decreased risk of rPFS events and a decreased risk of death, and an increased odds of radiographic response

Armstrong AJ, et al. J Clin Oncol 2022;40(suppl 16;abstr 5002).

CÁNCER DE PRÓSTATA

CPRCm

➢ ^{177}Lu-PSMA-617: factores predictores

TheraP

N=200

- **mCRPC post docetaxel suitable for cabazitaxel**
- **PD with rising PSA and PSA ≥ 20**
- **ECOG 0-2**
- **Previous ARi therapy allowed**
- **PET eligibility criteria***

Randomization 1:1

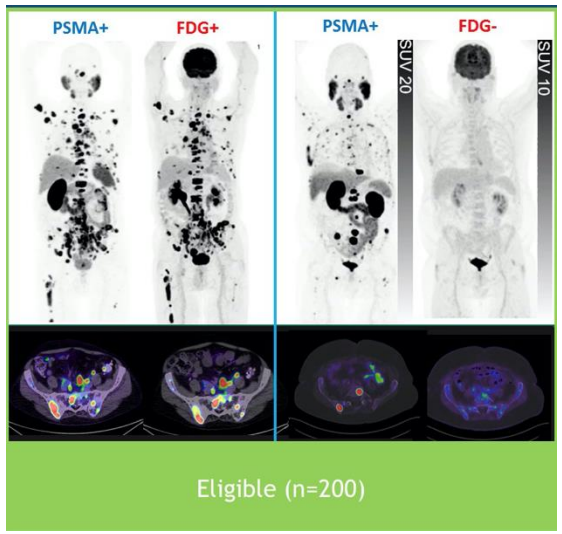
^{177}Lu-PSMA-617
8.5 GBq iv q6 weekly
↓ 0.5 GBq each cycle
Up to 6 cycles

Cabazitaxel
20 mg/m2 iv q3 weekly
Up to 10 cycles

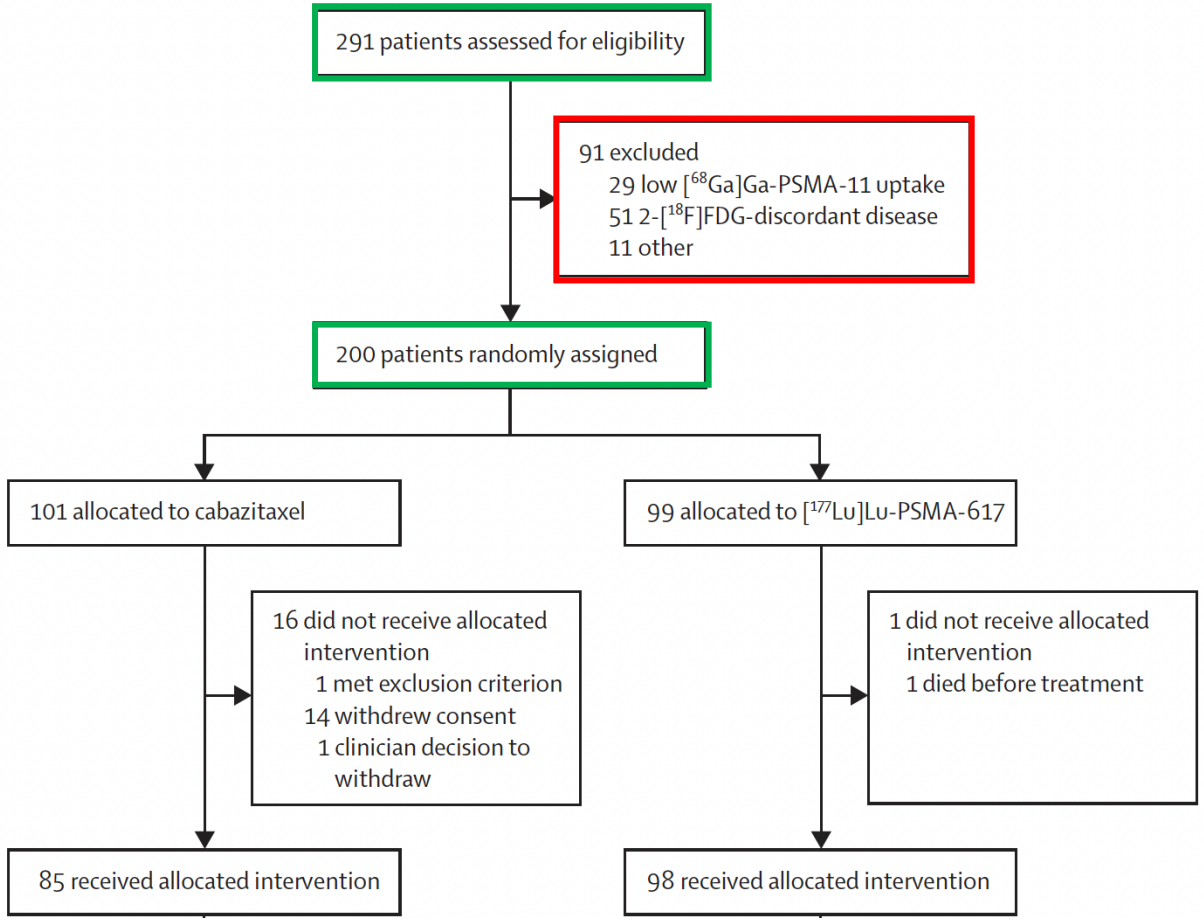
Primary endpoint: PSA_{50}-RR

Median follow-up -> 18.4 months

^{68}Ga-PSMA + 18F-FDG PET/CT
- PSMA SUVmax ≥ 20 at any site
- Measurable sites SUVmax > 10
- No FDG positive/PSMA negative sites of disease
- Centrally reviewed



Screening and randomization



Hofman MS, et al. Lancet 2021;397:797.

CÁNCER DE PRÓSTATA

CPRCm

➢ ^{177}Lu-PSMA-617: factores predictores

TheraP

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Randomization 1:1

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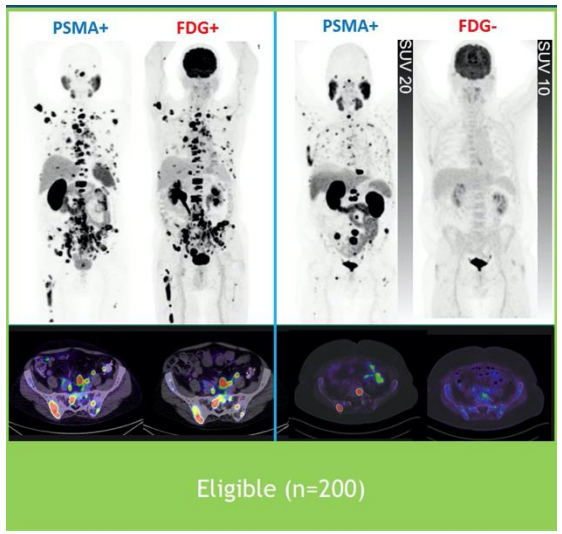
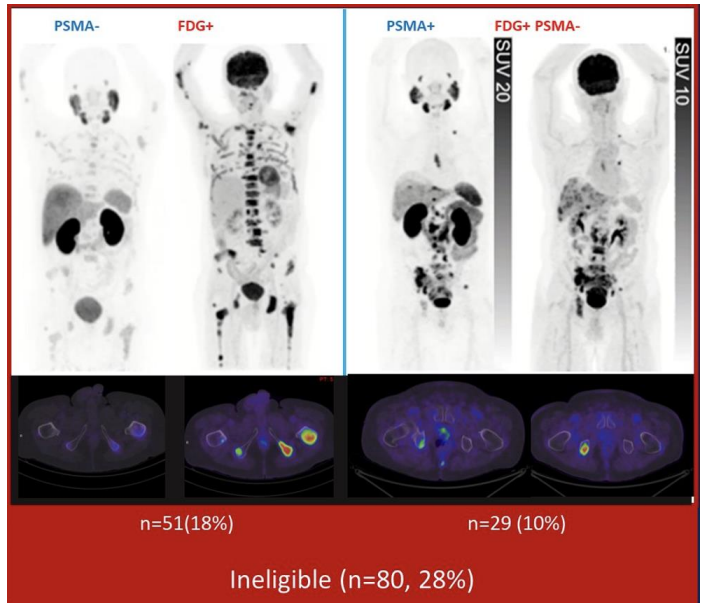
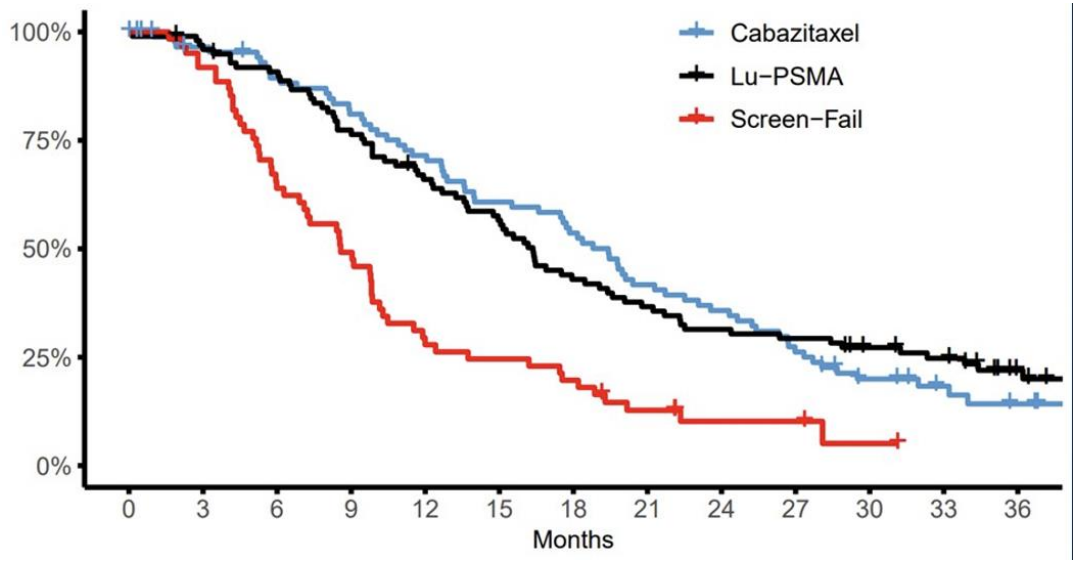


OS in Screen Failures





Hofman M, et al. J Clin Oncol 2022;40(suppl 16;abstr 5000).

CÁNCER DE PRÓSTATA

CPRCm

➤ ^{177}Lu-PSMA-617: factores predictores

TheraP

N=200

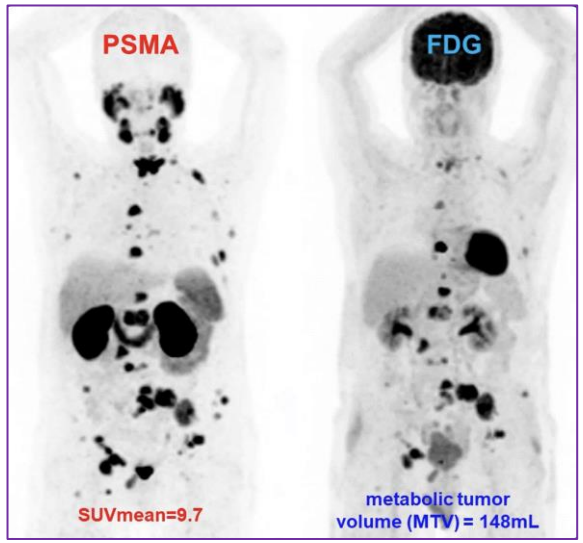
- mCRPC post docetaxel suitable for cabazitaxel
- PD with rising PSA and PSA ≥ 20
- ECOG 0-2
- Previous ARi therapy allowed
- PET eligibility criteria*

Randomization 1:1

^{177}Lu-PSMA-617
8.5 GBq iv q6 weekly
↓ 0.5 GBq each cycle
Up to 6 cycles

Cabazitaxel
20 mg/m2 iv q3 weekly
Up to 10 cycles

Primary endpoint: PSA_{50}-RR

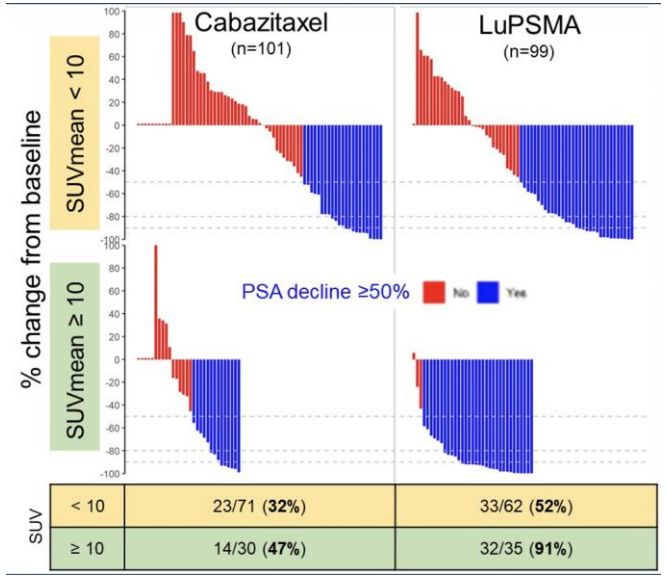


Baseline characteristics

Characteristic	Cabazitaxel (n = 101)	Lu-PSMA (n = 99)
PSMA SUVmean ≥ 10	30/101 (30%)	35/99 (35%)
FDG volume ≥200 mL	30/101 (30%)	30/99 (30%)

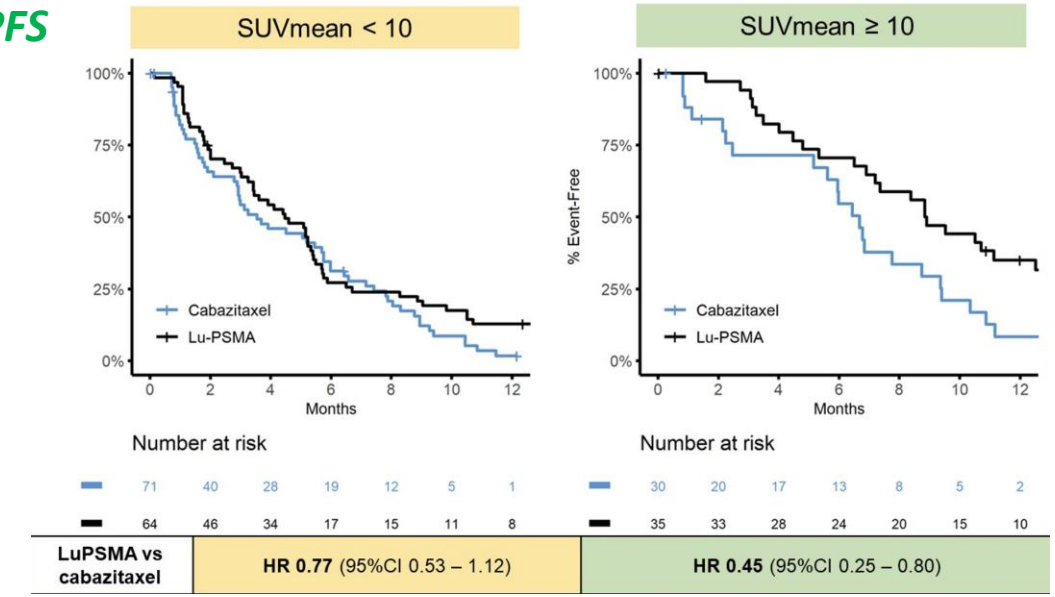
Efficacy by PSMA intensity

PSA_{50}-RR



SUV		
< 10	23/71 (**32%**)	33/62 (**52%**)
≥ 10	14/30 (**47%**)	32/35 (**91%**)

PSAPFS



LuPSMA vs cabazitaxel	HR 0.77 (95%CI 0.53 – 1.12)	HR 0.45 (95%CI 0.25 – 0.80)

Hofman M, et al. J Clin Oncol 2022;40(suppl 16;abstr 5000).

CÁNCER DE PRÓSTATA

CPRCm

➤ ^{177}Lu-PSMA-617: factores predictores

TheraP

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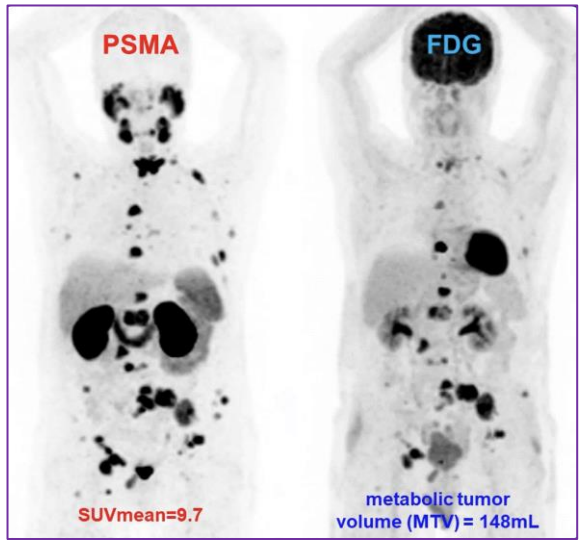
- mCRPC post docetaxel suitable for cabazitaxel
- PD with rising PSA and PSA ≥ 20
- ECOG 0-2
- Previous ARi therapy allowed
- PET eligibility criteria*

Primary endpoint: PSA_{50}-RR

Randomization 1:1

^{177}Lu-PSMA-617
8.5 GBq iv q6 weekly
↓ 0.5 GBq each cycle
Up to 6 cycles

Cabazitaxel
20 mg/m2 iv q3 weekly
Up to 10 cycles

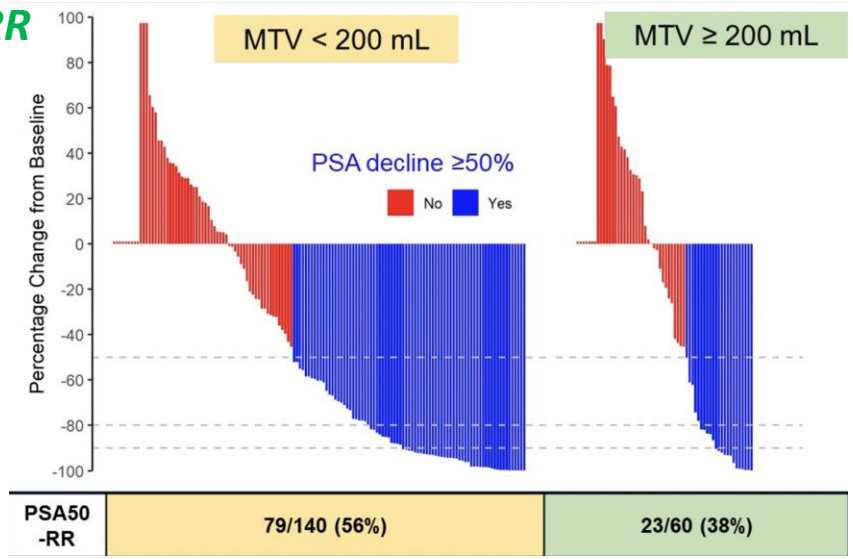


Baseline characteristics

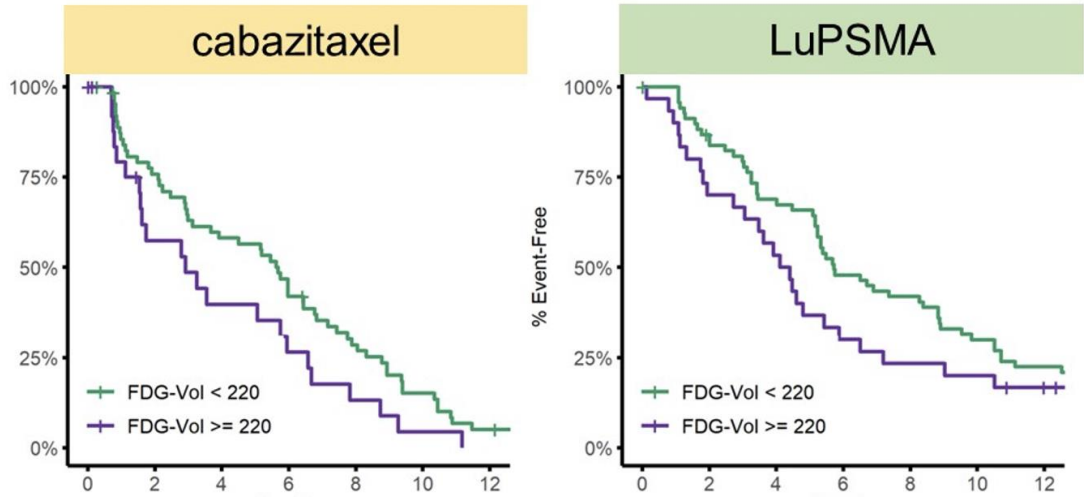
Characteristic	Cabazitaxel (n = 101)	Lu-PSMA (n = 99)
PSMA SUVmean ≥ 10	30/101 (30%)	35/99 (35%)
FDG volume ≥200 mL	30/101 (30%)	30/99 (30%)

Efficacy by FDG volume

PSA_{50}-RR



PFS



Hofman M, et al. J Clin Oncol 2022;40(suppl 16;abstr 5000).

PERFIL DE PACIENTE:
Perfil de toxicidad

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- ^{177}Lu-PSMA-617: efectos adversos

	Ensayo VISION (N=529)		Ensayo Thera-P (N=99)	
	Cualquier Gr	Gr ≥ 3	Cualquier Gr	Gr ≥ 3
Astenia	43,1%	5,9%	70%	5%
Boca seca	38,8%	0	60%	0
Ojos secos	-	-	30%	0
Náuseas	35,3%	1,3%	40%	1%
Anemia	31,8%	12,9%	19%	8%
Dolor	23,4%	3,2%	61%	11%
Artralgias	22,3%	1,1%	-	-
Pérdida de apetito	21,2%	1,9%	-	-
Estreñimiento	20,2%	1,1%	-	-
Diarrea	18,9%	0,8%	-	-
Vómitos	18,9%	0,9%	12%	1%
Trombopenia	17,2%	7,9%	18%	11%
Linfopenia	14,2%	7,8%	-	-
Leucopenia	12,5%	2,5%	10%	1%

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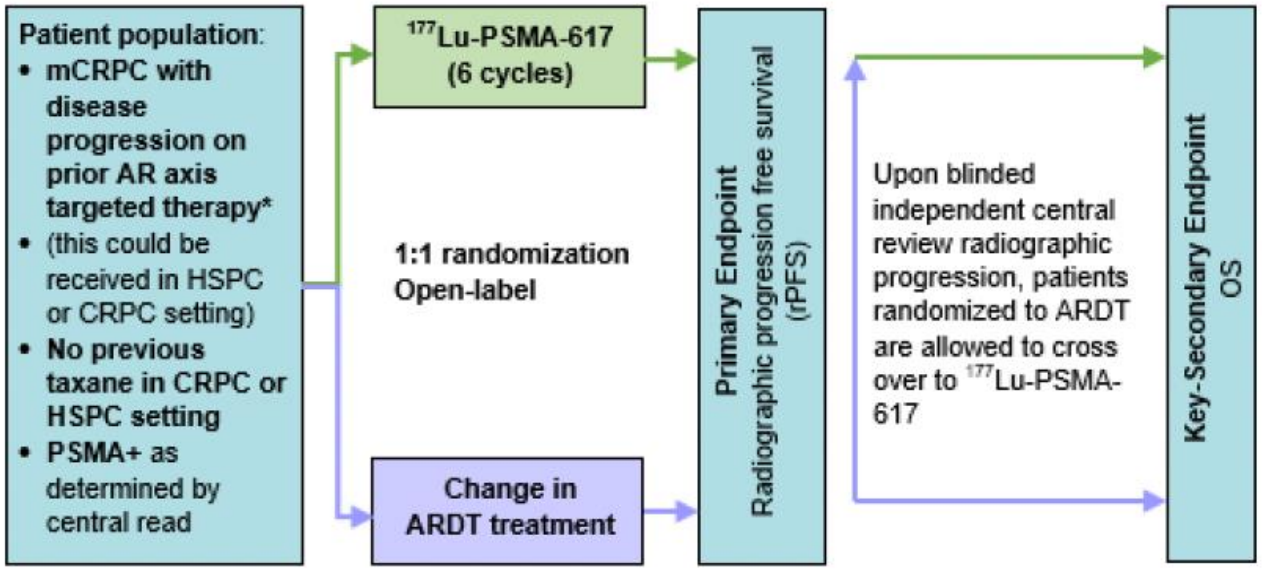
CPRCm

➢ ^{177}Lu-PSMA-617

PSMAfore

N=450



Primary endpoint: rPFS

^{68}Ga-PSMA-11 PET/TC scan positive (central reader)

Novartis Pluvicto™ shows statistically significant and clinically meaningful radiographic progression-free survival benefit in patients with PSMA–positive metastatic castration-resistant prostate cancer

Dec 05, 2022

Ad hoc announcement pursuant to Art. 53 LR

- *Phase III PSMAfore trial with Pluvicto™ met the primary endpoint of radiographic progression-free survival (rPFS) in PSMA–positive mCRPC who have been treated with androgen-receptor pathway inhibitor (ARPI) therapy[1]*
- *Pluvicto becomes the first PSMA-targeted radioligand therapy to demonstrate clinical benefit in mCRPC patients before receiving taxane-based chemotherapy[1], addressing a significant unmet need[2]*
- *Findings to be presented at an upcoming medical meeting and submitted to regulatory authorities for approval in 2023*
- *Novartis is advancing a broad portfolio of radioligand therapies to treat cancer and is investing in manufacturing capacity to meet the growing global demand for treatment*

Basel, December 5, 2022 — Today, Novartis announced the pivotal Phase III PSMAfore study with Pluvicto™ (INN: lutetium (^{177}Lu) vipivotide tetraxetan), a prostate-specific membrane antigen (PSMA)-targeted radioligand therapy, met its primary endpoint. Pluvicto demonstrated a statistically significant and clinically meaningful improvement in radiographic progression-free survival (rPFS) in patients with PSMA–positive metastatic castration-resistant prostate cancer (mCRPC) after treatment with androgen-receptor pathway inhibitor (ARPI) therapy, compared to a change in ARPI[1]. No unexpected safety findings were observed in PSMAfore; data are consistent with the already-well established safety profile of Pluvicto[1,3].

NCT04689828.

CÁNCER DE PRÓSTATA

CPRCm

^{177}Lu-PSMA-617: Perfil del paciente candidato

- ✓ CPRCm
- ✓ Que haya recibido al menos 1 IEA y un taxano (pendiente de resultados de PSMAfore y líneas previas)
- ✓ Positivo por ^{68}Ga-PSMA-PET
- ✓ Buena función orgánica:
  - Renal: eGFR ≥ 50 mL/min/1.73 m2
  - Hepática:
    - BbT < 2 x LSN (≤ 3 si Sd Glibert)
    - GPT / GOT ≤ 3 x LSN (≤ 5 si metástasis hepáticas)
  - Hematológica:
    - Hb 9.0 g/dL
    - Neutrófilos ≥ 1.5 x 10^9/L
    - Plaquetas ≥ 100.000