

Prostate Cancer Theranostics

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knowledge changing life



In accordance with the ACCME policy on relevant financial disclosure, all speakers/planners were asked to reveal relevant financial relationships.

Michael Holt, M.D. has disclosed the following commercial interests:

No financial disclosures

Prostate Cancer

- Most common non-cutaneous cancer in men
- 1.4 million new cases diagnosed this year with 375,000 deaths worldwide
- 1/8 men will be diagnosed with prostate cancer

Prostate Cancer

- Overall survival from onset of CRPC is poor
 - Without metastatic disease overall survival is approximately 30 months
 - With metastatic disease overall survival is approximately 12-13 months

Jewel, K et al 2024

Theranostics

Definition-

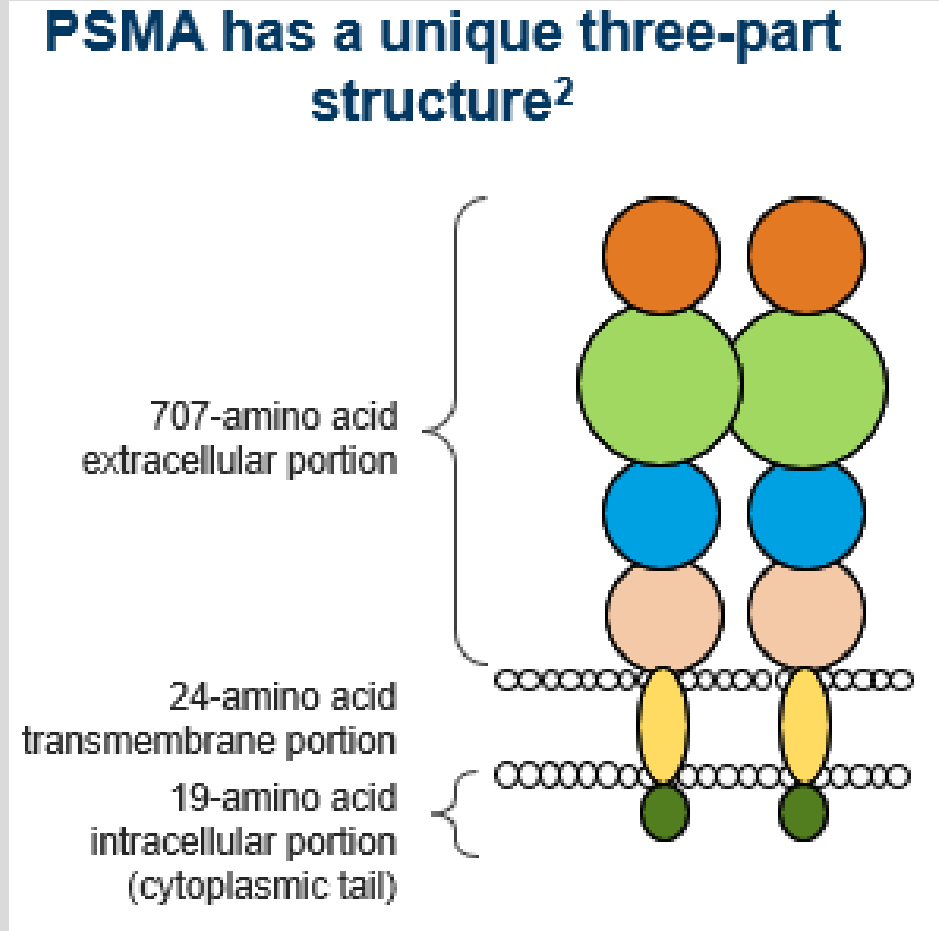
- Use of radiopharmaceuticals directed at a specific target along the cancer cell surface for the diagnosis, staging and treatment of the disease.
- It is a 2- phase process that has a diagnostic arm and a therapy arm
- Optimizes patient selection for radioligand therapy

Indications of PSMA PET/CT

- Initial staging of patients with intermediate to high-risk prostate cancer
- Restaging of patients with prostate cancer with evidence of biochemical relapse following definitive treatment
 - Potential of up to 30-40% of patients may develop biochemical recurrence
- Response Assessment

Prostate Specific Membrane Antigen (PSMA)

- Type II transmembrane glycoprotein located in the cell membrane of prostate epithelial cells
- Not specific to prostate gland!
- Expressed in normal tissue
 - duodenal mucosa
 - salivary glands
 - proximal renal tubular cells
 - neuroendocrine cells of colon
- Expressed in other tumors neovascularity
 - transitional cell, thyroid, lung, brain, renal cell and colon carcinomas

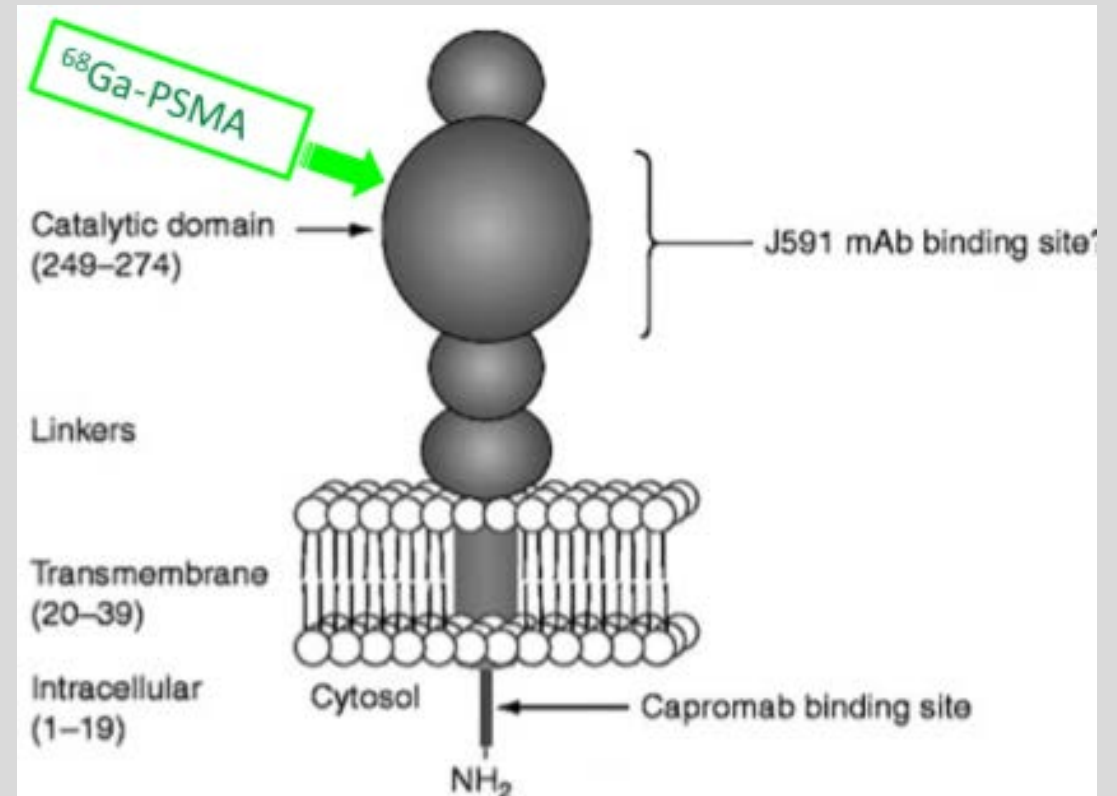


Rahbar K, et al

PSMA PET/CT Prostate Imaging

PSMA Imaging Agents

- ^{68}Ga -PSMA-11
- ^{18}F -DCFPyL
- ^{18}F -DCFBC
- Chelator-based PSMA-617
- PSMA inhibitor for imaging and therapy PSMA-I&T
- ^{18}F -PSMA-1007
- $^{99\text{m}}\text{Tc}$ -MIP-1404



Gomella, Leonard
Sidney Kimmel Cancer Center

PSMA PET/CT Prostate Imaging

- Ligands/antibody binds to extracellular component of PSMA
- PSMA antibody complex is internalized into endosomes by clathrin-coated pits

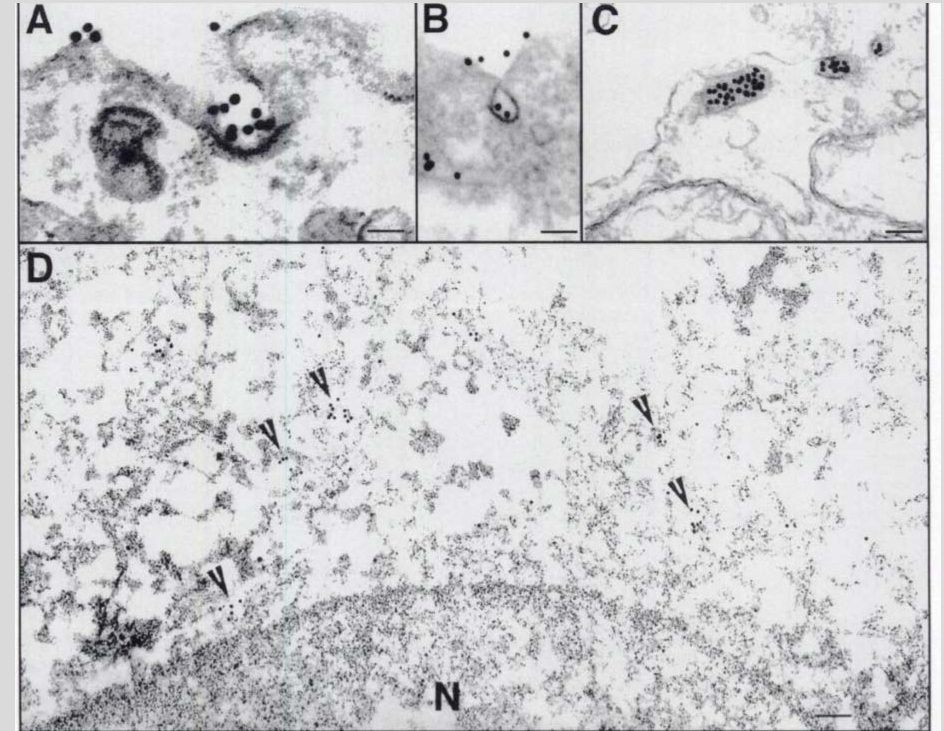


Fig. 3. IEM of the internalized mAb J591 in LNCaP cells. Cells were incubated with J591 at 37°C for 10 min (A–C) or 2 h (D) and processed for immunogold labeling as described in “Materials and Methods.” Note the accumulation of gold particles in clathrin-coated vesicles (A and B) and in vesicles proximal to the plasma membrane (C). At 2 h, note the accumulation of gold particles in a juxtannuclear region (arrowheads). N, nucleus. Bars represent 34 (A), 65 (B and C), and 85 nm (D), respectively.

mAb J591

Liu, He et al 1998

What Makes PSMA a Good Target?

- PSMA overexpressed in >90% of prostate cancer
- PSMA expression increases with grade of tumor
- PSMA expression is significantly higher in metastatic lymph nodes and distal metastases compared to the primary tumor
- PSMA expression is significantly higher in metastatic castrate resistant prostate cancer with deleterious DNA repair aberrations compared to those without
- PSMA expression is increased in mCRPC compared to CSPC
- PSMA expression is increased with androgen deprivation therapy

Novartis

1. Rahbar K, et al. *Mol Imaging*. 2018;17:1536012118776068; 2. Fendler WP, et al. *JAMA Oncol*. 2019;5(6):856-863; 3. Hofman MS, et al. *Lancet*. 2020 395(10231):1208-1216; 4. Zeng S, et al. *Oncotarget* 2017;8(7):12247-12258; 5. Minner S, et al. *Prostate*. 2011;71(3):281-288; 6. Hupe MC, et al. *Front Oncol*. 2018;8:623; 7. Wright GL Jr, et al. *Urol Oncol*. 1995;1(1):18-28; 8. Paschalis A, et al. *Eur Urol*. 2019;76(4):469-478; 9. Wright GL Jr, et al. *Urology*. 1996;48(2):326-234; 10. Bravaccini S, et al. *Sci Rep*. 2018; 8: 4254; 11. Donin NM, et al. *J Nucl Med*. 2018;59(2):177-182; 12. Liu H, et al. *Cancer Res*. 1998;58(18):4055-4060; 13. Eder M, et al. *Bioconj Chem*. 2012;23(4):688-697; 14. Zippel C, et al. *Pharmaceuticals (Basel)*. 2020;13(1):12; 15. Berliner C, et al. *Eur J Nucl Med Mol Imaging*. 2017;44(4):670-677; 16. Bluemel C, et al. *EJNMMI Res*. 2016;6(1):78.

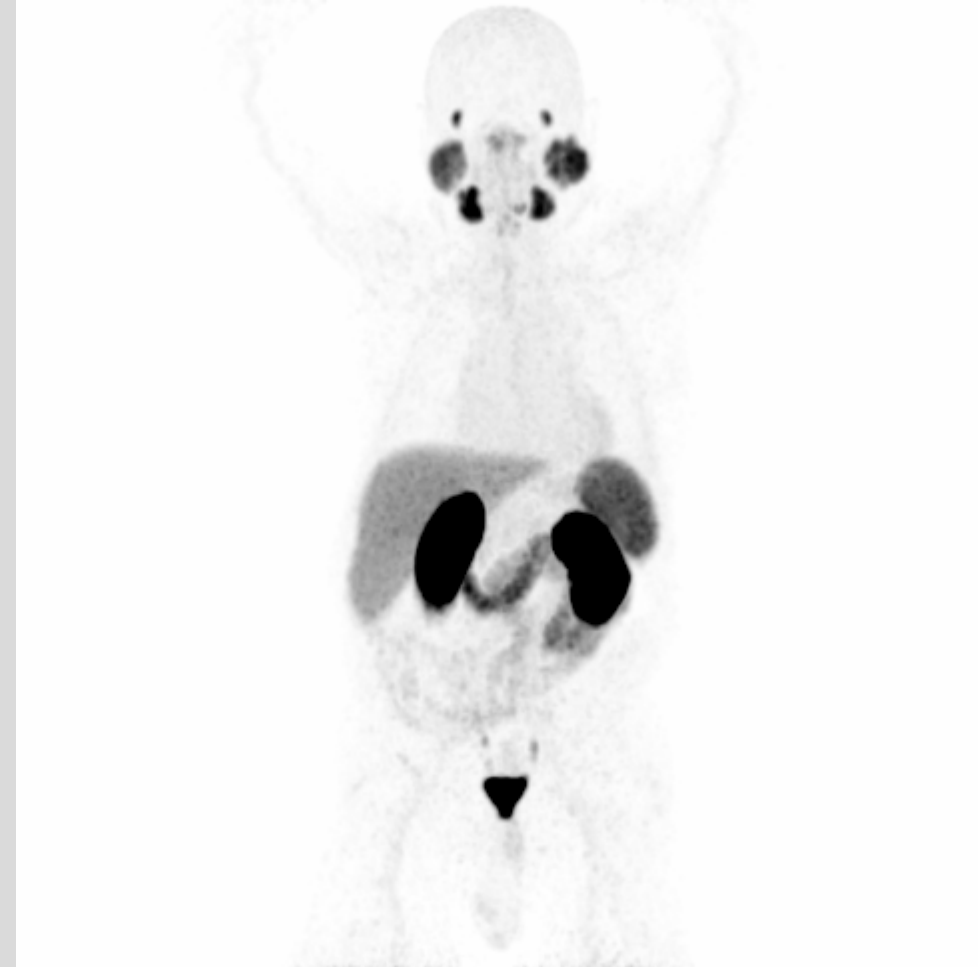
PSMA PET/CT Normal Biodistribution

Biodistribution

- Lacrimal glands, salivary glands, liver, spleen, small intestines, colon and kidneys

Excretion

- Primarily renal excreted with mild hepatobiliary excretion



PSMA PET/CT vs. Conventional Imaging

- Australian multi-center prospective randomized study of 302 patients with high-risk prostate cancer prior to radical prostatectomy or definitive XRT
- High-risk features included at least one of the following:
 1. PSA>20 ng/ml
 2. International Society of Uro pathology grade group 3-5
 3. Clinical stage T3 or worse

	Sensitivity	Specificity	Accuracy
PSMA PET/CT	85%	98%	92%
Conventional imaging	38%	91%	65%

Hofman, MS et al 2020

PSMA PET/CT Staging on Clinical Decision-Making in Patients with Intermediate or High-Risk Prostate Cancer

Retrospective study- 116 patients with simulated tumor board

Clinical information- age, PSA level, Gleason score, number of positive biopsy cores, conventional imaging results

Management recommendation- before and after results of the PSMA PET/CT(MR)

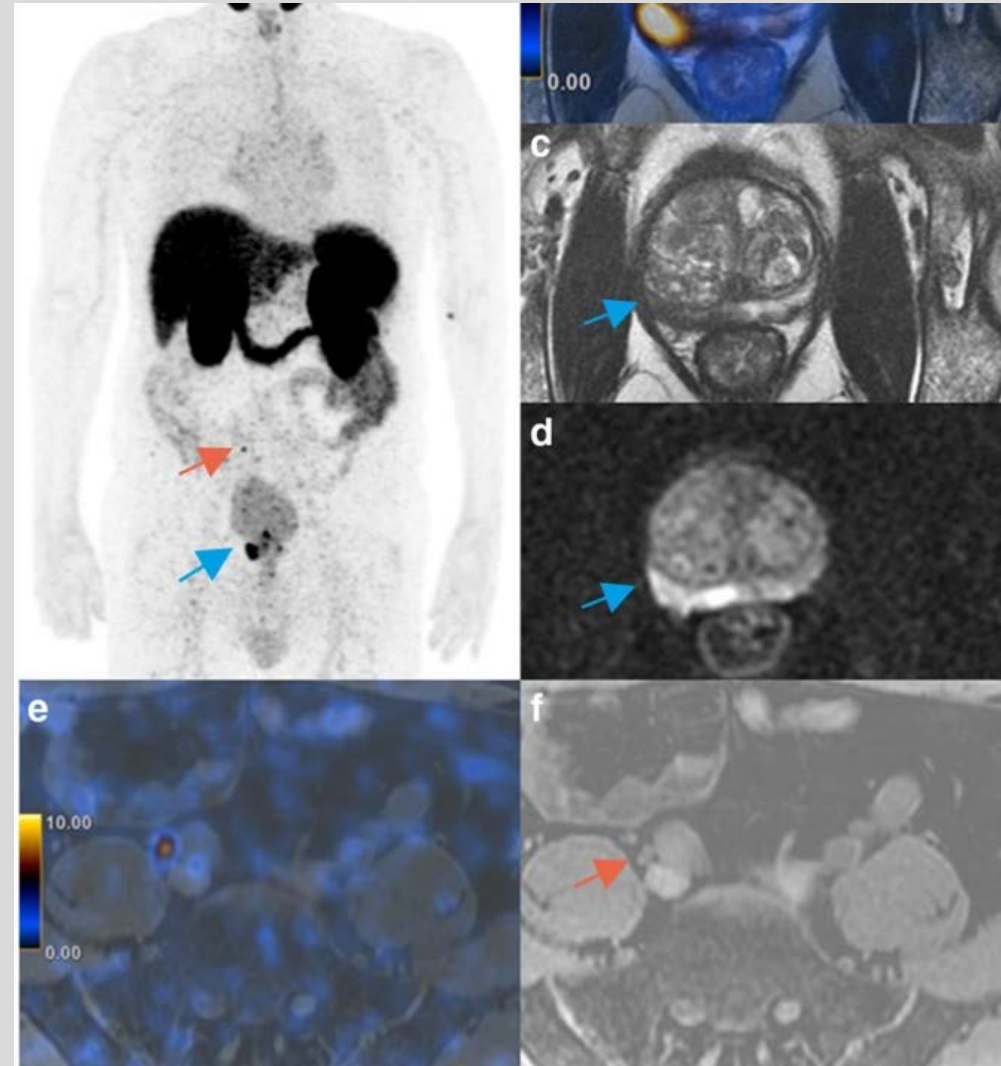
Change in Management

1. Change in therapy modality
 - a. Switch in modality therapy
 - b. Addition/subtraction of a modality (surgery, XRT, systemic therapy, high intensity US, surveillance)
2. Change in modality detail
 - a. change in XRT field
 - b. change in dissection field
 - c. change in systemic therapy (chemo vs. ADT)

Ferraro, D et al 2020

PSMA PET/CT Staging on Clinical Decision-Making in Patients with Intermediate or High-Risk Prostate Cancer

- PSMA PET/CT changed treatment management in 27% of patients
- Most common change in therapy modality was addition of systemic therapy to the local treatment
- Most common change in modality detail was change in XRT field



Ferraro, D et al 2020

PSMA PET/CT Evaluation of Biochemical Recurrence

Multicenter (UCLA,UCSF) prospective study- total 635 patients

- 262 (41%) s/p radical prostatectomy
- 169 (27%) s/p XRT
- 204 (32%) s/p both

Lesion validation

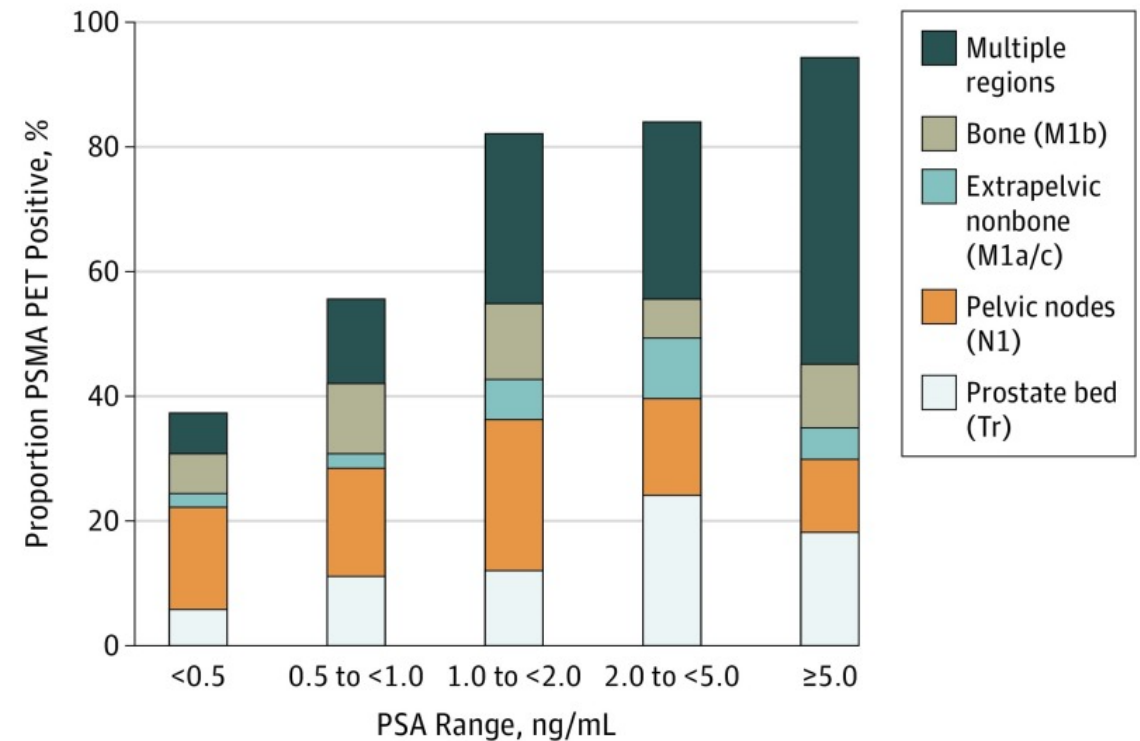
- Histopathology
- Follow up conventional imaging
- PSA levels following target therapy

Fendler, W et al 2019

Table 2. ⁶⁸Ga-PSMA-11 PET Detection Rate on a Patient Basis

Table 2. ⁶⁸Ga-PSMA-11 PET Detection Rate on a Patient Basis

Stratification	No.	PET-Positive Results, No. (%)	χ^2 P Value
All patients	635	475 (75)	
PSA			
<0.5	136	52 (38)	<.001
0.5- <1.0	79	45 (57)	
1.0- <2.0	89	75 (84)	
2.0- <5.0	158	136 (86)	
≥5.0	173	167 (97)	
PSA doubling time, mo^a			
<6	248	191 (77)	.80
≥6	245	182 (74)	
Not available	142	102 (72)	
PSA nadir after prostatectomy^b			
<0.1	230	146 (63)	.18
≥0.1	111	81 (73)	
Not available	125	92 (74)	

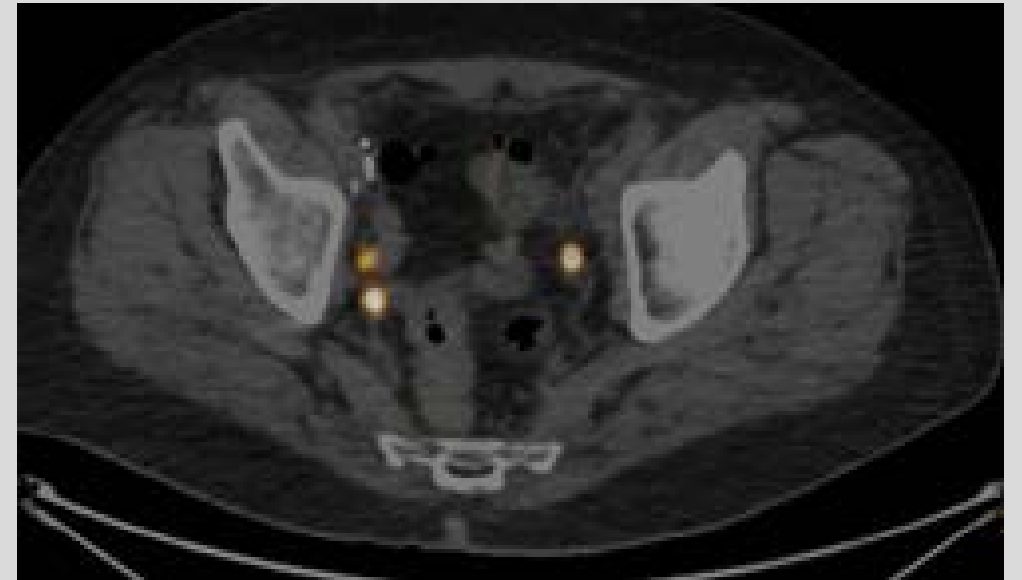


Fendler, W et al 2019

67 yo T3aN0M0 Prostate Cancer with Biochemical Recurrence Following Prostatectomy

PSA- <0.01 11/26/23

PSA- 0.2 8/20/24



PSMA PET/CT 8/28/24

PSMA PET/MR

Could potentially serve as the preferred imaging modality in the initial staging of intermediate to high-risk prostate cancer.

MRI- offers excellent morphologic evaluation of the prostate and surrounding soft tissues given its high spatial resolution and soft tissue differentiation

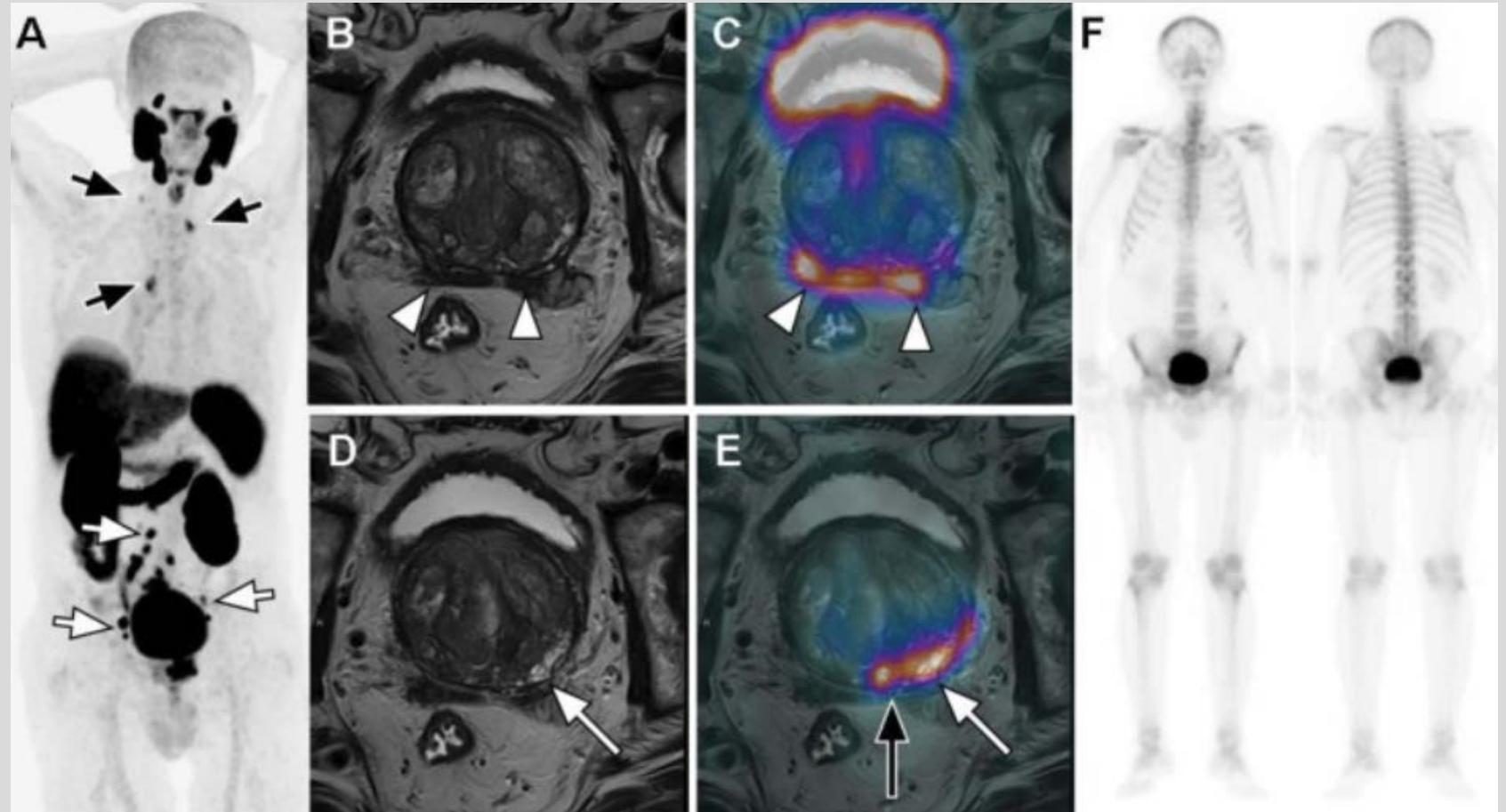
PSMA PET- modality of choice for evaluation of metastatic disease to lymph nodes, bones and visceral organs

PSMA PET/MR

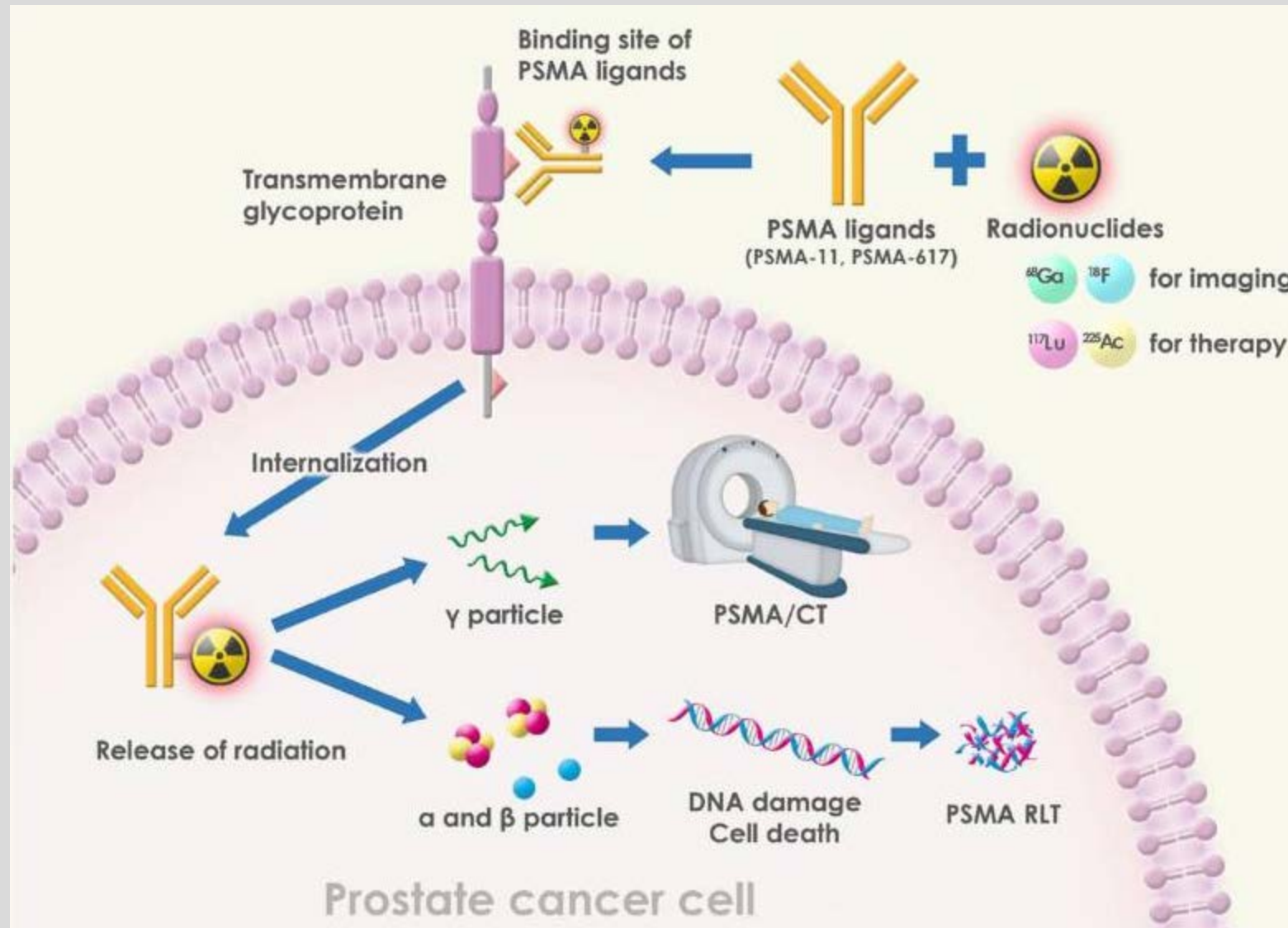
77 y/o with high-risk PCa

- Gleason score: 7
- PSA: 44 ng/ml

Galiza Barbosa F et al



PSMA Targeted Radioligand Therapy



Uemura, M et al 2023

MCW Theranostics Center

- Multidisciplinary approach
 1. Nuclear Medicine Radiologists
 2. Medical Oncologists
 3. Radiation Oncologists
- Nurse Coordinator
 1. Coordinates appointments and follow up visits for the patients
 2. Patient education of treatment and post treatment precautions
 3. Available for patient questions
- NM technologists/Nursing/Radiation safety support

MCW 177Lu-PSMA-617 Therapy Program

- Volumes as of August 2024
 1. 156 patients
 2. Average number of treatments per patient = 4
 3. A total of 538 doses administered

Dose Administration

- Hydration is very important
- Prophylactic antiemetic therapy
- Cooling of salivary glands- controversial



MCW 177 Lu-PSMA-617 (Vision Trial)

- International prospective phase 3 trial consisting of 831 patients
- Advanced MCRPC patients with positive ^{68}Ga -PSMA-11 scans who were previously treated with at least 1 androgen receptor pathway inhibitor and 1/2 taxane chemotherapy agents.
- Randomized in a 2:1 ratio to receive either ^{177}Lu -PSMA-617 (7.4 GBq q 6 weeks for 4-6 doses) and SOC vs. SOC.
- SOC excluded immunotherapy, chemotherapy, Ra-223 and investigational drugs
- Primary endpoints were radiology progression-free survival and overall survival

Sartor, O et al 2021

Phase 3 Vision Trial Results

- Imaging based PFS
 1. ^{177}Lu -PSMA-617 plus SOC - 8.7 months
 2. SOC- 3.4 months

- Overall Median Survival
 1. ^{177}Lu -PSMA-617 plus SOC- 15.3 months
 2. SOC- 11.3 months

Sartor, O et al 2021

177 Lu-PSMA-617 (Vision Trial)

Adverse Events

Event	¹⁷⁷ Lu-PSMA-617 plus Standard Care (N = 529)		Standard Care Alone (N = 205)	
	All Grades number of patients (percent)	Grade ≥3	All Grades	Grade ≥3
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 ¹⁷⁷ Lu-PSMA-617 dose	30 (5.7)	10 (1.9)	NA	NA
Adverse event that led to interruption of ¹⁷⁷ Lu-PSMA-617 [‡]	85 (16.1)	42 (7.9)	NA	NA
Adverse event that led to discontinuation of ¹⁷⁷ 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)

177Lu-PSMA-617 Super Responders

¹⁷⁷ Lu-PSMA-617	PSA
2/10/23	1500
5/11/23	137
6/19/23	23
7/31/23	8
9/11/23	0.53
10/23/23	0.39



PSMA PET/CT
12/15/22

¹⁷⁷ Lu-PSMA-617 vs. Cabazitaxel (TheraP trial)

- Australian multicenter prospective phase 2 study (2021)
- 200 patients MCRPC randomized 1:1 to ¹⁷⁷ Lu-PSMA-617 (6-8.5 GBq IV q 6 weeks up to 6 cycles or Cabazitaxel (20mg/m² IV q 3 weeks up to 10 cycles)
- Previous treatment with androgen receptor-directed therapy was allowed
- Both ⁶⁸ Ga-PSMA-11 and FDG PET/CT scans were performed
 - PET eligibility criteria:
 1. SUV max at site of disease at least 20
 2. SUV max greater than 10 at sites of metastatic disease
 3. No FDG positive/PSMA negative lesions
- Primary endpoint: PSA response with reduction of at least 50% from baseline

Hofman, M et al 2021

¹⁷⁷Lu-PSMA-617 vs. Cabazitaxel (TheraP trial)

Findings:

- PSA responses were more frequent in patients receiving ¹⁷⁷Lu-PSMA-617 than Cabazitaxel- 66% vs 37%
- Grade 3/4 toxicities were less frequent in the ¹⁷⁷Lu-PSMA-617 group- 33% vs 53%
- SUV mean > 10 predicted a better PSA response in patients receiving ¹⁷⁷Lu-PSMA-617 compared to Cabazitaxel

Hofman, M et al 2021

PSMAfore trial

- Multicenter prospective phase 3 clinical trial of mCRPC patients with confirmed PSMA expression who are taxane-naïve, have received one prior androgen receptor pathway inhibitor and are candidates for a change in ARPI
- Approximately 450 patients randomized 1:1 to receive either
 ^{177}Lu -PSMA-617 (7.4 GBq q 6weeks x 6 cycles) or
change in ARPI (abiraterone or enzalutamide)
- Primary endpoint- rPFS
- Secondary endpoint- OS
- Results expected 1st quarter 2025

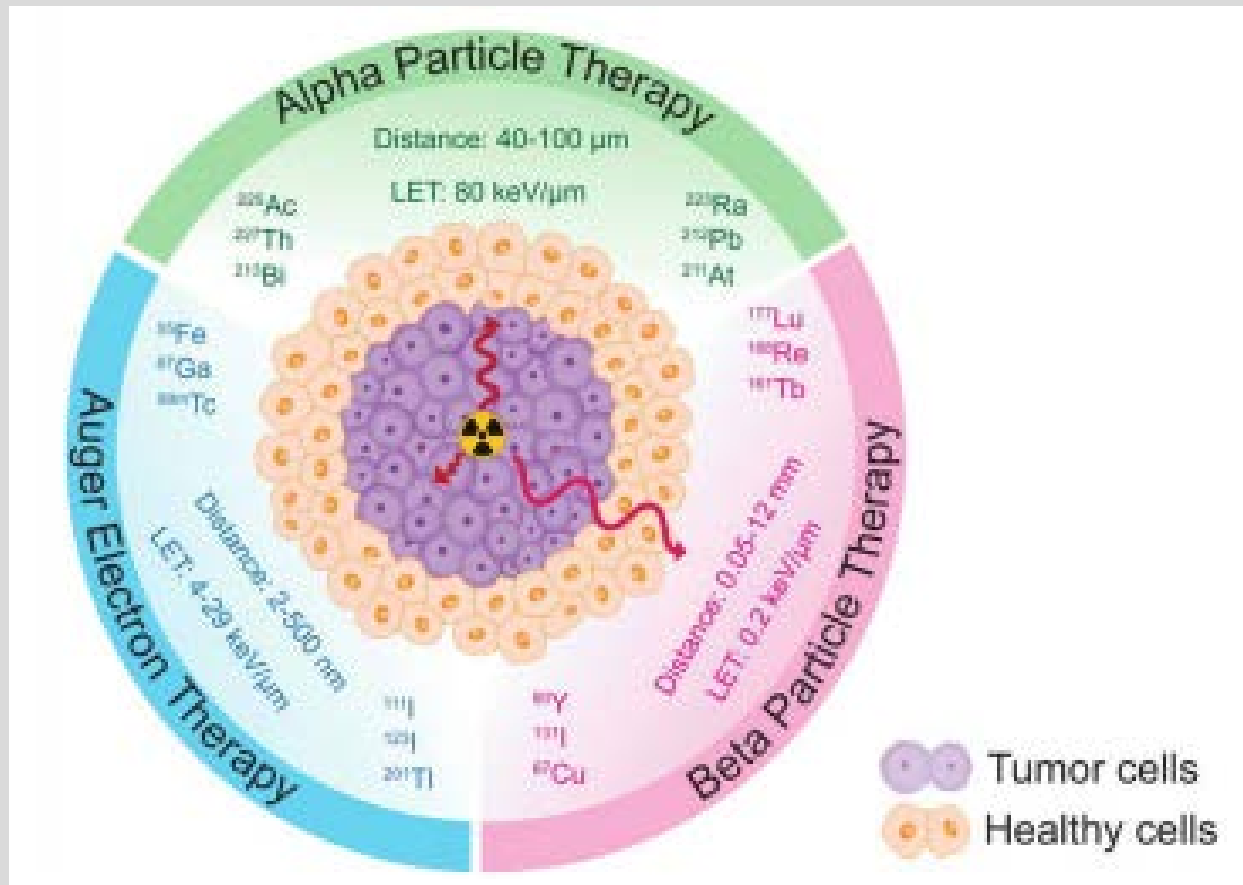
Sartor, O et al 2022

PSMAAddition Trial

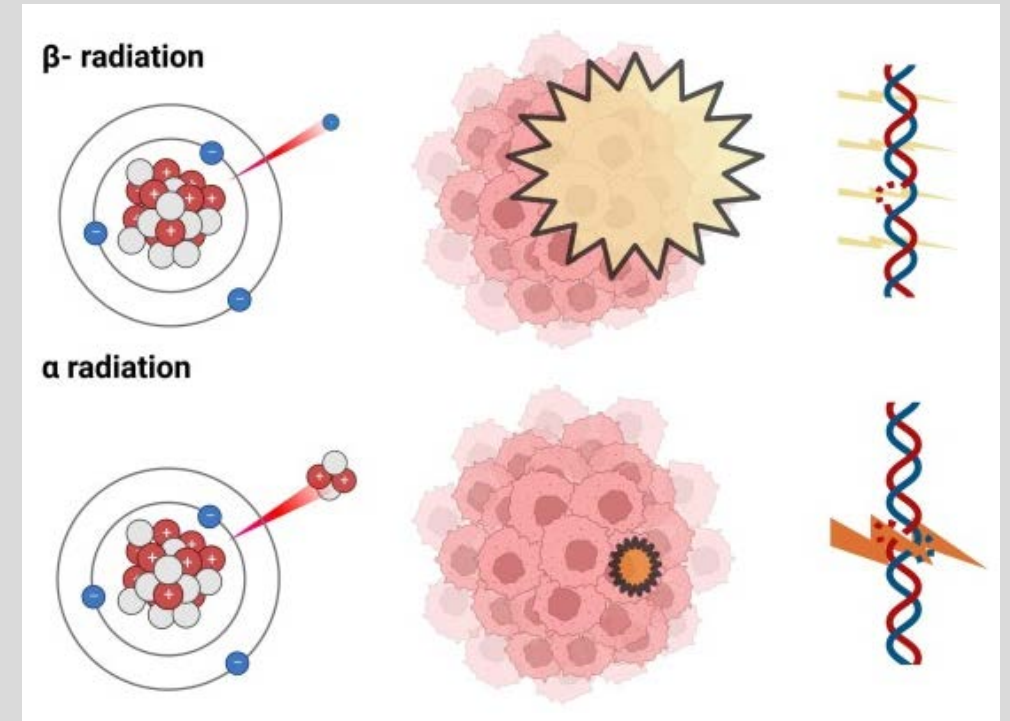
- ADT and androgen receptor pathway inhibitors (ARPI) increase PSMA expression and likely increases radio-sensitization
- International prospective phase 3 trial consisting of 1126 patients with metastatic PSMA PET positive hormone sensitive prostate cancer
- Randomized 1:1 to receive ^{177}Lu -PSMA-617 (7.4 GBq q 6 weeks for maximum 6 cycles) and SoC (ADT and ARPI) vs SoC alone
- Primary endpoint is rPFS- cross over allowed
- Secondary endpoint is OS

Tagawa, S et al 2023

Targeted Alpha Particle Therapy for Prostate Cancer



Bidkar, A et al 2024



Bauckneht, M et al 2024

225Ac-PSMA-617 in chemotherapy-naïve patients with advanced metastatic prostate cancer

- South African study consisting of 17 patients with chemotherapy-naïve metastatic prostate cancer and lack of access to second generation anti-androgen therapy (abiraterone and enzalutamide)
- Positive avidity (SUVmax 2x > liver) on 68Ga-PSMA-11 PET/CT
- Treated with de-escalating doses of 225Ac-PSMA-617 (8,7,6,4 MBq) q 8 weeks
- PSA levels q 4 weeks and 68Ga-PSMA-11 PET/CT prior to each cycle.

Sathekge, M et al 2018

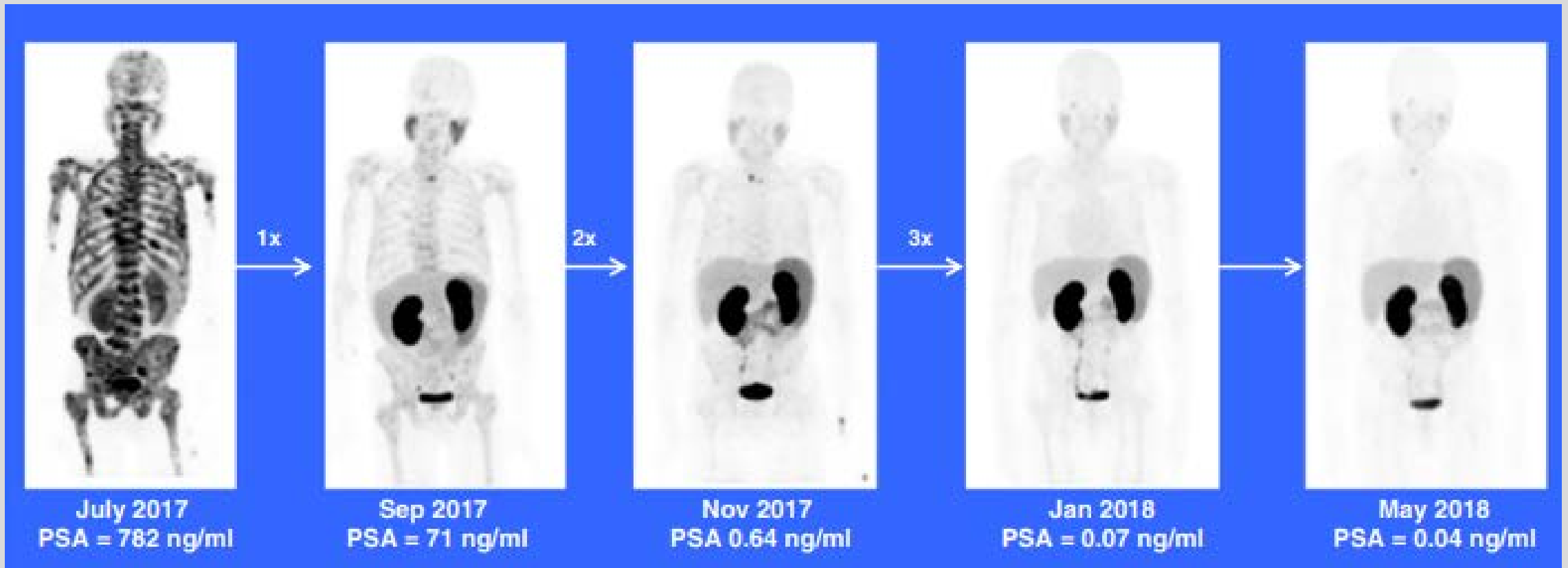
225Ac-PSMA-617 in chemotherapy-naïve patients with advanced metastatic prostate cancer

Findings:

1. PSA decline > 90% was seen after treatment (2/3 cycles)
2. 68Ga-PSMA-11 PET/CT- >50% decline in SUVmax in 15/17 patients including 11 patients with complete resolution.
3. Grade 1/2 xerostomia. None was severe.

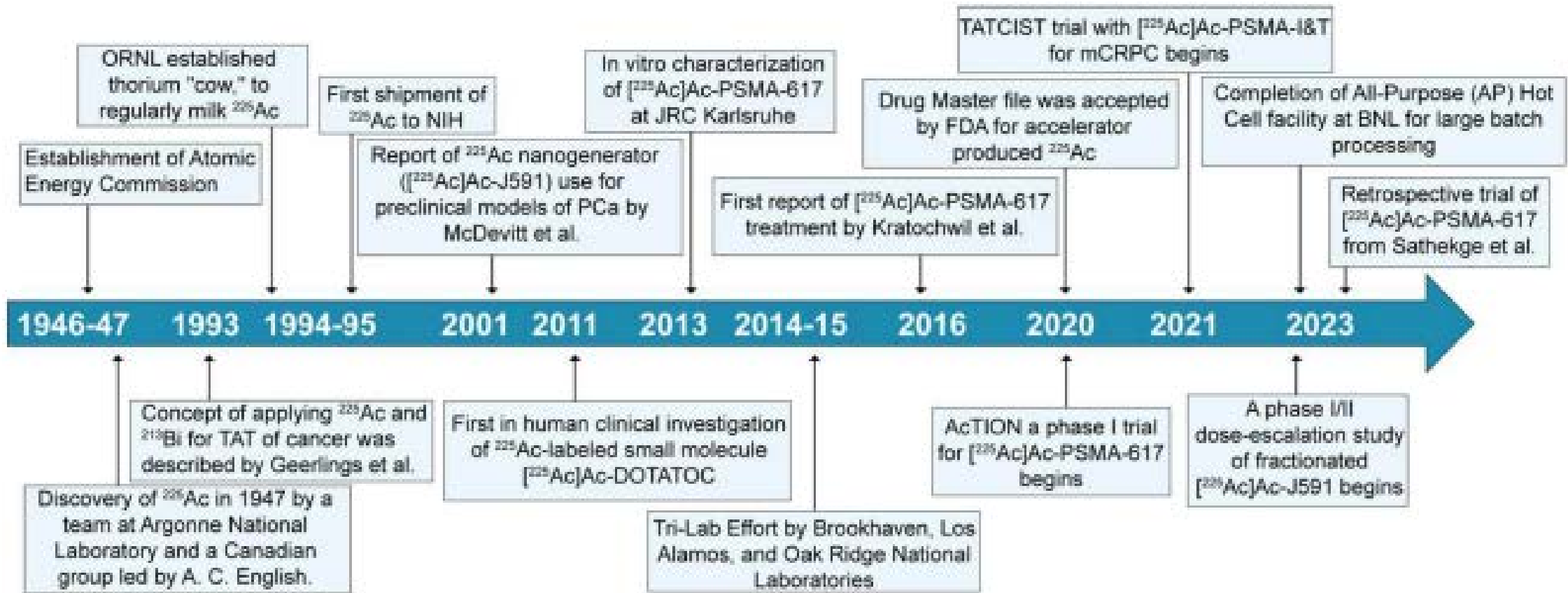
Sathekge, M et al 2018

225Ac-PSMA-617 in chemotherapy-naïve patients with advanced metastatic prostate cancer



Sathekge, M et al 2018

Targeted Alpha Particle Therapy for Prostate Cancer



Bidkar, A et al 2024

PRRT Combination Trials (synergistic effect)

LuPARP Clinical Trial

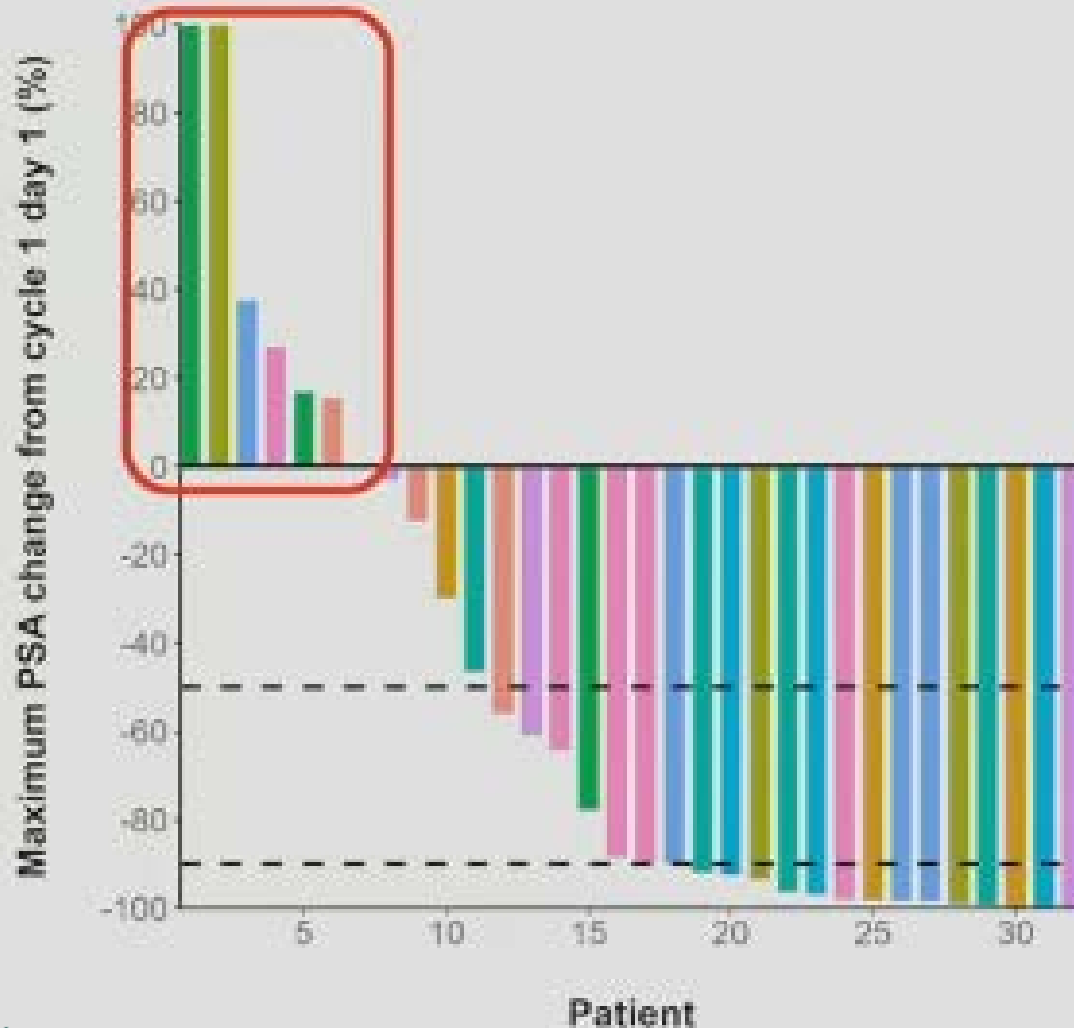
- ^{177}Lu -PSMA-617 beta emissions typically result in single stranded DNA breaks which are repaired by PARP enzymes. The combination of Olaparib (PARP inhibitor) with ^{177}Lu -PSMA-616 would result in greater radio-sensitization and increased DNA damage
- Australian multicenter dose escalation phase 1 trial of 48 mCRPC patients who had progressed on androgen receptor signaling inhibitors
- PSMA and FDG PET/CT exams performed. Inclusion criteria:
 - PSMA SUV max > 15 at any site
 - PSMA SUV max > 10 at other sites
 - No FDG discordance

Sandhu, S ASCO 2023

LuPARP Clinical Trial Results

LuPARP results: PSA Response

Sandhu, S ASCO 2023



- Cohort 1: 50mg Day 2-15
- Cohort 2: 100mg Day 2-15
- Cohort 3: 150mg Day 2-15
- Cohort 4: 200mg Day 2-15
- Cohort 5: 250mg Day 2-15
- Cohort 6: 300mg Day 2-15
- Cohort 7: 200mg Day -4-14
- Cohort 8: 300mg Day -4-14
- Cohort 9: 300mg Day -4-18

	LuPARP	TheraP	VISION
PSMA SUVmax	>15	>20	> Liver
PSA50 response	66% (21/32)	66% (67/99)	46% (177/385)
PSA80 response	53% (17/32)	48% (48/99)	33% (127/385)
PSA90 response	44% (14/32)	38/99 (38%)	N/A
ORR by RECIST 1.1	78% (7/9)	49% (48/99)	30% (95/319)

1. Sartor O et al. N-Engl J Med 2021;385(12):1091-1103.
 2. Hofman MS et al. Lancet 2021;397(10276):797-804

Combination therapies of ^{177}Lu PSMA-617 and immune checkpoint inhibitors (Evolution trial)

- Hypothesis
 - ^{177}Lu -PSMA-617 will in combination with immune checkpoint inhibitors result in improved long term clinical outcomes by altering the tumor immune microenvironment
- Multicenter phase 2 study consisting of 100 patients with PSMA positive mCRPC disease who have progressed on androgen receptor pathway inhibitors, have received no more than one line of prior chemotherapy, and no FDG positive disease
- Randomized 2:1 to ^{177}Lu -PSMA-617 plus ipilimumab and nivolumab vs ^{177}Lu -PSMA-617 alone
- Primary endpoint- 1 year PSA progression-free survival
- Secondary endpoints- PSA response rate, adverse events, rPFS and OS

Sandhu, S et al 2023

Patient Selection for Prostate PSMA Targeted Radioligand Therapy

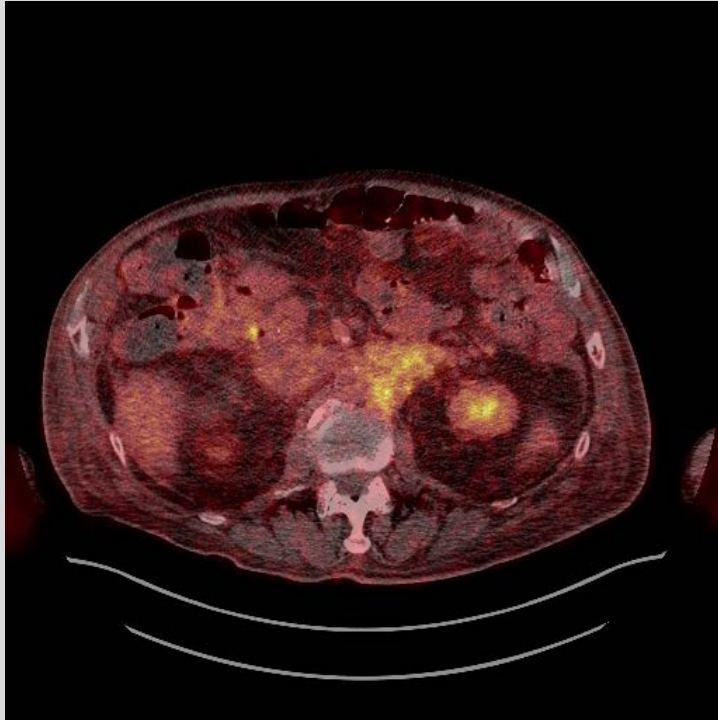
- What defines PSMA positivity?
 1. Heterogeneous tumor PSMA expression
 2. Different definitions for the Vision and TheraP trials
 3. Additional research is needed

Prognostic Indicators from PSMA PET/CT

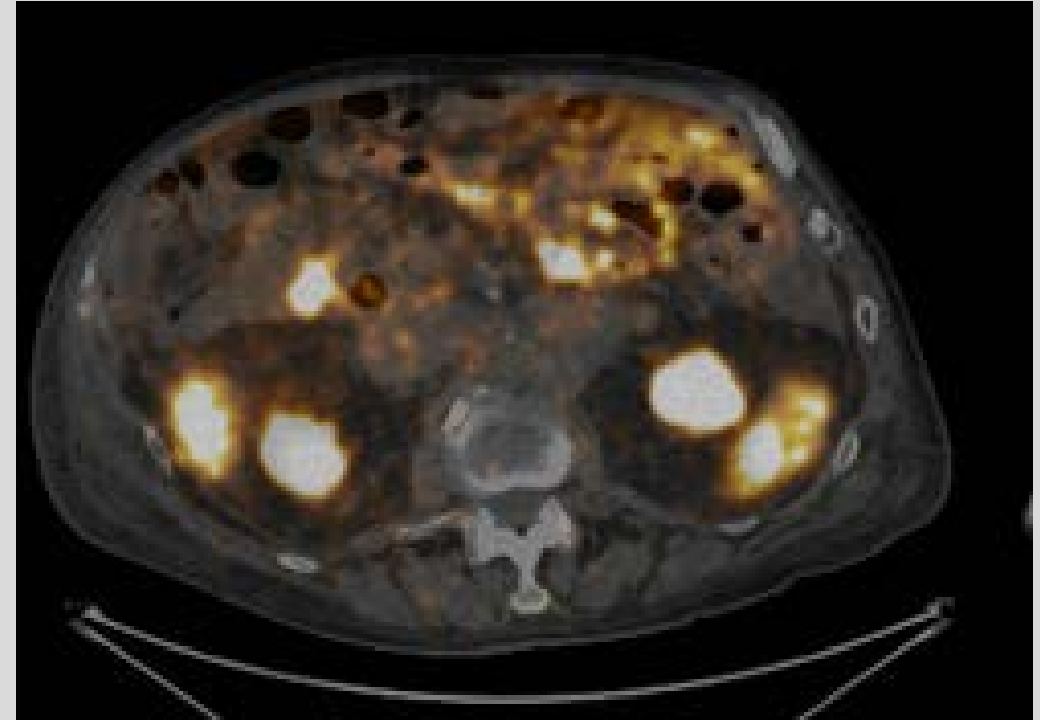
- SUV mean >10 associated with better response (Thera P trial)
- Uptake exceeding parotid glands had a favorable outcome
- PSMA and FDG PET/CT concordant/discordant activity

PSMA and FDG Discordance

86 yo with mCRPC



FDG PET/CT 12/1/23



PSMA PET/CT 12/4/23

Dosimetry in Targeted Radioligand Therapy

- The goal is to personalize the targeted radioligand therapy to each patient to maximize the therapeutic effect while minimizing potential toxicity
- ^{177}Lu emits beta particles (therapy arm) and gamma rays (main photopeak is 208 keV)
- Dosimetry measurements are acquired by performing CT/SPECT imaging after each treatment to assess mean absorbed doses to kidneys, parotids, bone marrow etc. as well as median whole-body tumor dose
- Treat what you see and see what you treat

Therapeutic Radiopharmaceuticals currently in Clinical Trials

Cancer has nowhere to run

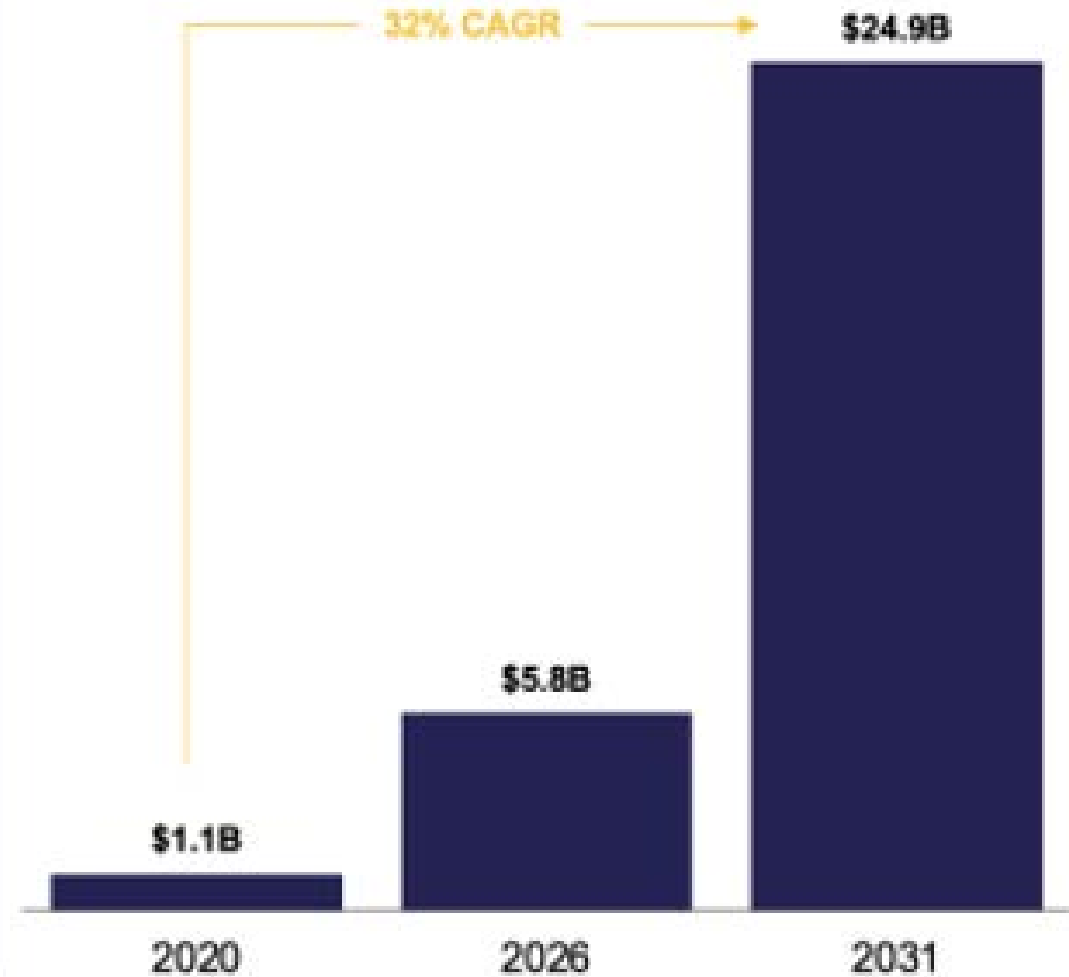
Partial list of theranostic drugs focused on major areas of disease and progress toward US approval.

<p>1 Breast Cancer Cases in the US: 5,399,000</p> <p>NCT04207029 ¹⁷⁷Lu-DAY270242B Phase I</p> <p>NCT03746431 ¹⁷⁷Lu-PP1-0434 Phase II</p>	<p>10 Brain Cancer Cases in the US: 180,047</p> <p>NCT00688945 ¹⁷⁷Lu-390 Phase II</p> <p>NCT05635891 ¹⁷⁷Lu-Epitolizer Phase I</p>	<p>20 Merkel Cell Carcinoma Cases in the US: >3,000</p> <p>PH01 ¹⁷⁷Lu-DOTA-TATE Phase II</p>
<p>2 Prostate Cancer Cases in the US: 3,340,976</p> <p>Prostate Cancer - Last Line Ravicic (¹⁷⁷Lu-PSMA-617) Approved</p> <p>Prostate Cancer Bone Metastases Xeligen (¹⁷⁷Lu-PSMA-617) Approved</p> <p>Prostate Cancer (mCRPC; Pre-Chemo) PSMAfore ¹⁷⁷Lu-PSMA-617 Phase III</p> <p>SPLASH ¹⁷⁷Lu-PP1-2062 Phase III</p> <p>Prostate Cancer (mCRPC) PPSMARion ¹⁷⁷Lu-PSMA-617 Phase III</p> <p>USAM ¹⁷⁷Lu-PP1-2002 Phase II</p>	<p>11 Neuroendocrine Tumors Cases in the US: 171,000</p> <p>Neuroendocrine Tumors - Grade 1 and 2 Lutathera (¹⁷⁷Lu-DOTA-TATE) Approved</p> <p>Neuroendocrine Tumors - Grade 3 NCT02419202 ¹⁷⁷Lu-DOTA-TATE Phase III</p> <p>COMPOSE ¹⁷⁷Lu-DOTA-TOC Phase III</p>	<p>21 Pediatric Brain and Neurological Cancers Cases in the US: >2,000</p> <p>LuSO-11 ¹⁷⁷Lu-DOTA-TATE Phase II</p> <p>NCT03275402 ¹⁷⁷Lu-Orbiteranib Phase III</p>
<p>3 Melanoma Cases in the US: 1,612,976</p> <p>NCT05855533 ¹⁷⁷Lu-AMT01 Phase II</p> <p>NCT05130255 ¹⁷⁷Lu-DOTA-62D-SADA Phase I</p>	<p>12 Multiple Myeloma Cases in the US: 170,400</p> <p>NCT05190200 ¹⁷⁷Lu-Sulfasalazin Phase II</p> <p>ELVSR-WM ¹⁷⁷Lu-Sulfasalazin Phase II</p>	<p>22 Pheochromocytomas & Paragangliomas Cases in the US: 400+</p> <p>Azarda (¹⁷⁷Lu-tobengastat) Approved</p>
<p>4 Colorectal Cancer Cases in the US: 1,380,022</p> <p>NCT03465822 ¹⁷⁷Lu-PP1-2009 Phase I</p> <p>NCT03432183 ¹⁷⁷Lu-PP1-0308 Phase I</p>	<p>13 Sarcoma Cases in the US: 543,898</p> <p>NCT05130255 ¹⁷⁷Lu-DOTA-62D-SADA Phase I</p> <p>LUPRE01 ¹⁷⁷Lu-FAP-2206 Phase II</p>	<p>Total Cases in the US 14,307,796</p>
<p>5 Thyroid Cancer Cases in the US: 951,193</p> <p>¹³¹I-Nat Approved</p>	<p>14 Gastric Cancer Cases in the US: 1,227,211</p> <p>NCT05605522 ¹⁷⁷Lu-PP1-2009 Phase I</p> <p>NCT05636309 ¹⁷⁷Lu-PP1-1566 Phase II</p>	<p>What are theranostic radiotracers? Most theranostic drugs are composed of a radioligand linked to a ligand.</p> <p>Ligands Ligands stick to disease-specific molecules in the body.</p> <p>PSMA-617 FAP-2206 DOTA-TATE</p> <p>390 Next</p>
<p>6 B-Cell Non-Hodgkin's Lymphoma Cases in the US: 700,781</p> <p>Zovista (¹⁷⁷Lu-Estivatoranib Carcortar) Approved</p>	<p>15 Pancreatic Cancer Cases in the US: 98,389</p> <p>NCT03074522 ¹⁷⁷Lu-AMT01 Phase I</p> <p>NCT05977322 ¹⁷⁷Lu-F308 Phase I</p>	<p>Radiolabels</p> <p>¹⁸F ¹⁷⁷Lu Visualize by appearing bright on a PET scan.</p> <p>¹⁷⁷Lu ¹⁷⁷Lu Treat by killing diseased cells with targeted radiation.</p>
<p>7 Lung Cancer Cases in the US: 650,000</p> <p>NCT03636305 ¹⁷⁷Lu-PP1-2006 Phase II</p> <p>NCT0666618 ¹⁷⁷Lu-VMT-m-MET Phase II</p>	<p>16 Acute Myeloid Leukemia Cases in the US: 33,330</p> <p>STPBA ¹⁷⁷Lu-Sarab-B Phase III</p>	<p>Theranostic Radiotracers Highly effective precision drugs safely activating non-invasive diagnosis and therapy.</p> <p>¹⁸F-PSMA-617 ¹⁷⁷Lu-PP1-2006</p>
<p>8 Kidney & Renal Pelvis Cancer Cases in the US: 620,325</p> <p>NCT0666618 ¹⁷⁷Lu-VMT-m-MET Phase II</p> <p>NCT05706129 ¹⁷⁷Lu-PP1-4452 Phase II</p>	<p>17 Glioblastoma Cases in the US: 38,834</p> <p>NCT0339942 ¹⁷⁷Lu-NeuB Phase I</p> <p>TRN-1 ¹⁷⁷Lu-39A Phase II</p>	
<p>9 Ovarian Cancer Cases in the US: 235,511</p> <p>NCT03636305 ¹⁷⁷Lu-PP1-2006 Phase II</p> <p>NCT03746431 ¹⁷⁷Lu-PP1-0434 Phase II</p>	<p>18 Gastroesophageal Adenocarcinoma (GEA) Cases in the US: >50,000</p> <p>NCT05977322 ¹⁷⁷Lu-PP1-2006 Phase I</p>	
	<p>19 Cholangiocarcinoma (CCA) Cases in the US: <6,000</p> <p>NCT05432183 ¹⁷⁷Lu-PP1-0308 Phase I</p>	

Market Growth

(\$ in billions)

U.S. Radiotherapeutics Sales (\$)¹



BAMF Health

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