



**AKY-2519**

# Clinical Imaging and Dosimetry Data

May 27, 2026

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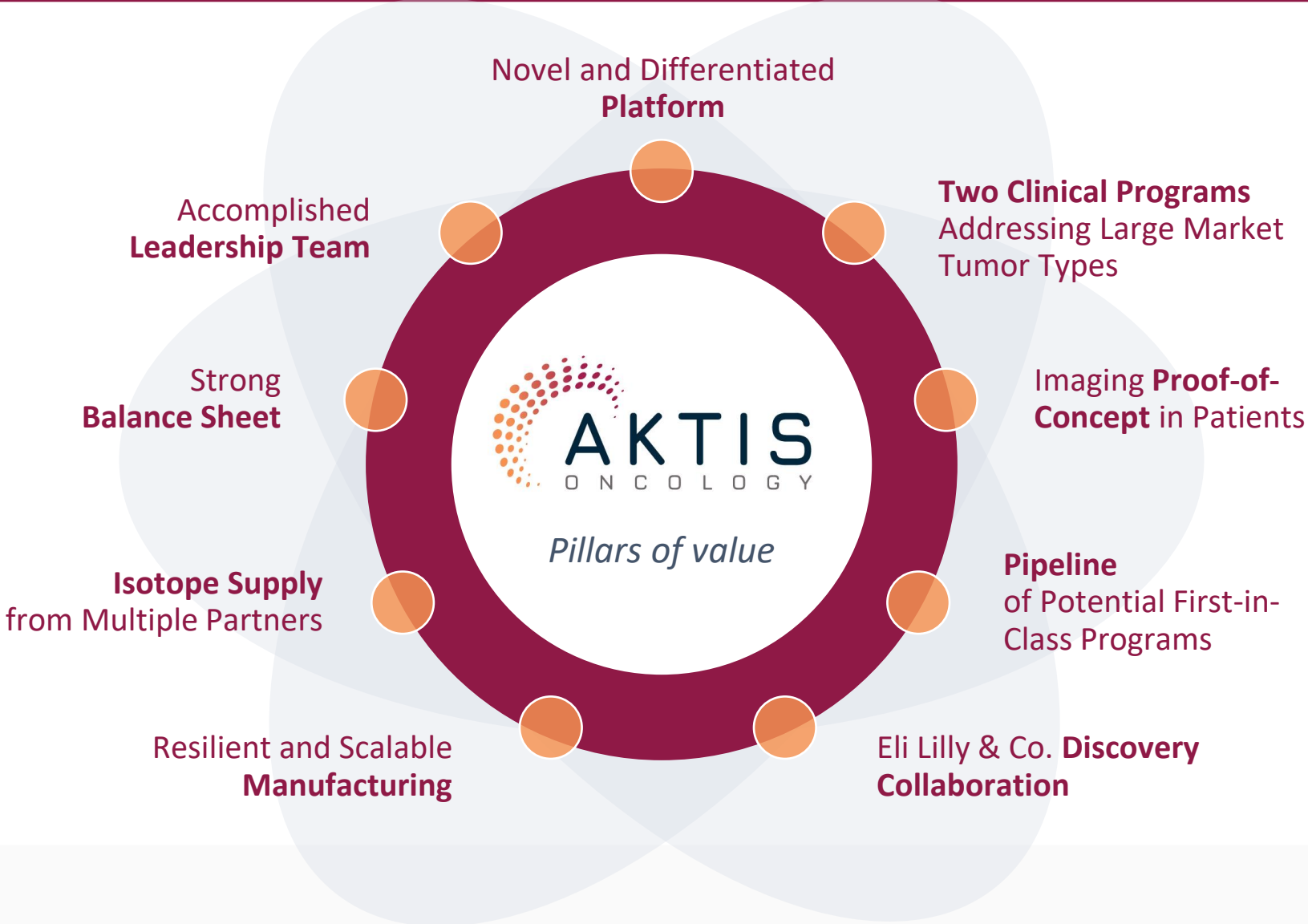
# Agenda

**Aktis Corporate Overview & Upcoming Milestones**

**B7-H3 Overview & AKY-2519 Clinical Imaging and Dosimetry Data**

**Fireside Chat with Oliver Sartor, M.D., and Timothy Yap, MBBS, Ph.D.**

# Maximizing the impact of radiopharmaceuticals

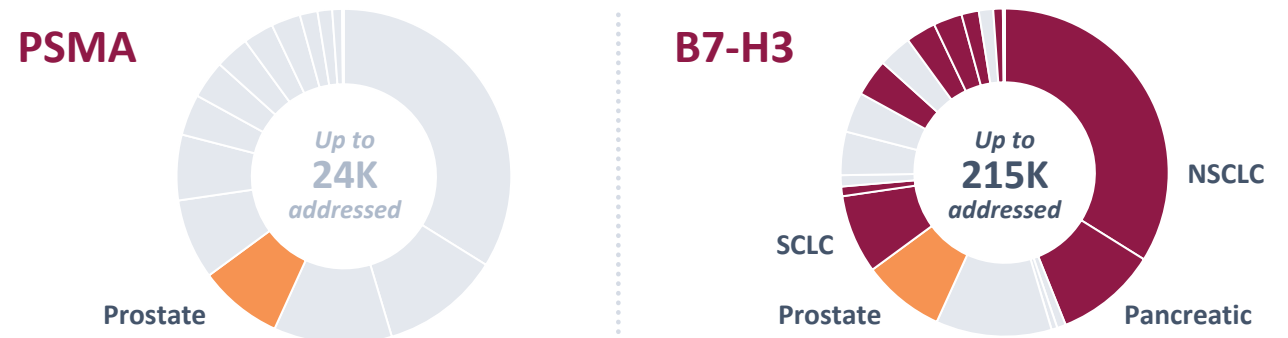


# Significant opportunity for B7-H3 as a differentiated radiopharmaceutical target in mCRPC and other indications

- PLUVICTO® estimated global peak sales ~\$5.4 billion in prostate cancer alone<sup>1</sup>
- Persistent unmet needs remain due to:
  - PSMA downregulation or PSMA-low expression
  - Aggressive/ poorly differentiated cancer with PSMA expression loss
  - PSMA expression in the salivary glands
- 90% of mCRPC patients express B7-H3
  - Low expression in normal tissues, including salivary glands
- B7-H3 targeting RLT has the potential for differentiated biodistribution compared to PSMA-targeted therapies

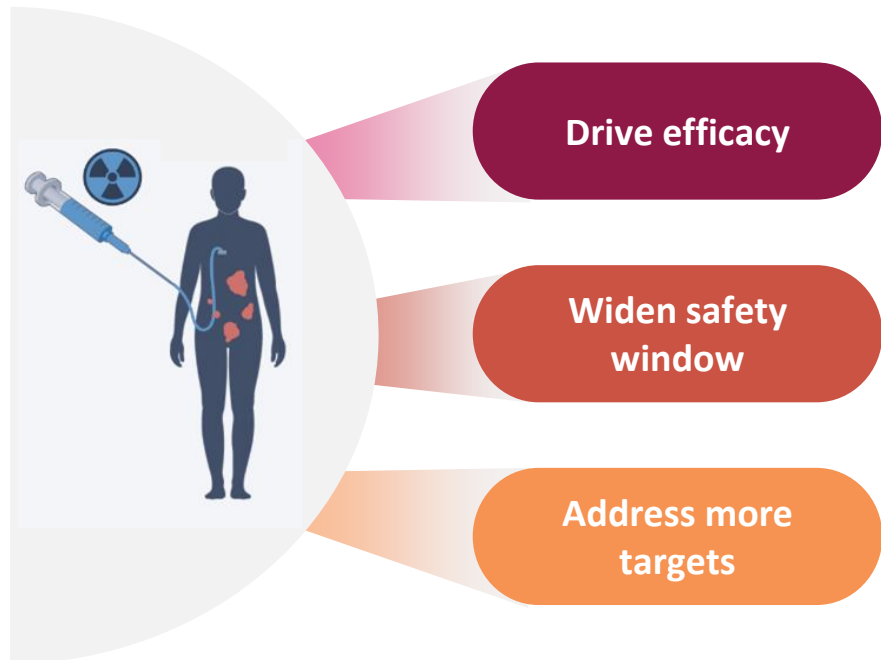
B7-H3 is highly expressed in multiple solid tumors; Potential to unlock whitespace opportunities

Indication	Metastatic incidence in US <sup>2</sup>	Initial Positioning	B7-H3 expression positive <sup>3</sup>
Prostate cancer	~23.9k	2L+	90%
NSCLC	~99.7k	2L+	80%
SCLC	~22.9k	2L+	70%



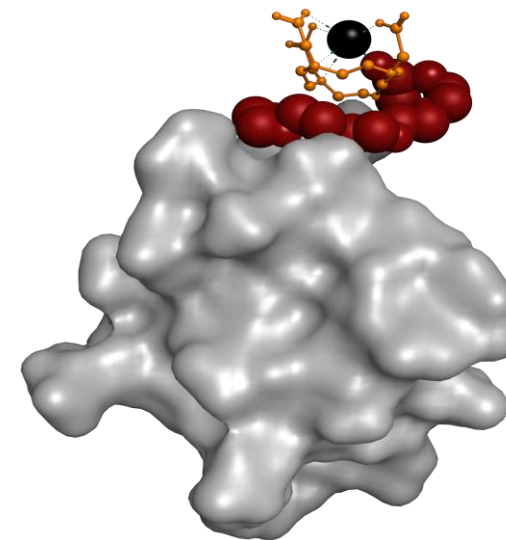
# Patient-centric approach to maximizing radiopharmaceutical impact

## GOAL TO MAXIMIZE PATIENT BENEFIT



- ✓ Increase addressable tumor types
- ✓ Enable use in earlier lines of therapy
- ✓ Broaden prescriber base to oncology

## DESIGNED TO EXPAND RADIOPHARMACEUTICAL IMPACT



**Isotope-agnostic to image and treat**


**Non-cleavable linker**

**Folded miniprotein target binder**  
(~40-60aa)

- ✓ High tumor penetration
- ✓ Fast clearance for safety
- ✓ **Broad universe of addressable targets**

**Miniprotein radioconjugate profile: Antibody-like binding, with small peptide-like pharmacology**

# Aktis is advancing a novel pipeline for large patient populations

PROGRAM	TARGET/INDICATION	DISCOVERY	IND-ENABLING	PHASE 1b	PHASE 2/3	UPCOMING MILESTONES
<b>AKY-1189</b>	Nectin-4 expressing solid tumors	Fast Track Designation*				Ph1b ongoing Prelim data in 1Q'27
<b>AKY-2519</b>	B7-H3 expressing mCRPC					Imaging/ dosimetry data at ASCO 2026 Ph1b initiated Prelim data in 2027
	B7-H3 expressing lung, colorectal, and other solid tumors					Imaging/ dosimetry data at ASCO 2026 Ph1b start 2H'26
<b>Multiple Programs</b>	Undisclosed					
 <b>Lilly</b> A MEDICINE COMPANY	Undisclosed					

# Clinical imaging and dosimetry data for AKY-2519 to be presented at the 2026 ASCO Annual Meeting

## **AKY-2519, a novel B7-H3-targeted radioconjugate, and its biodistribution profile in patients with mCRPC\***

**DATE AND TIME:** May 30, 1:30 p.m. - 4:30 p.m. CDT

**PRESENTER:** Michael Sathekge, Professor and Head of Nuclear Medicine department at University of Pretoria, South Africa and Steve Biko Academic Hospital

Imaging and biodistribution data **support ongoing Phase 1b trial for mCRPC**

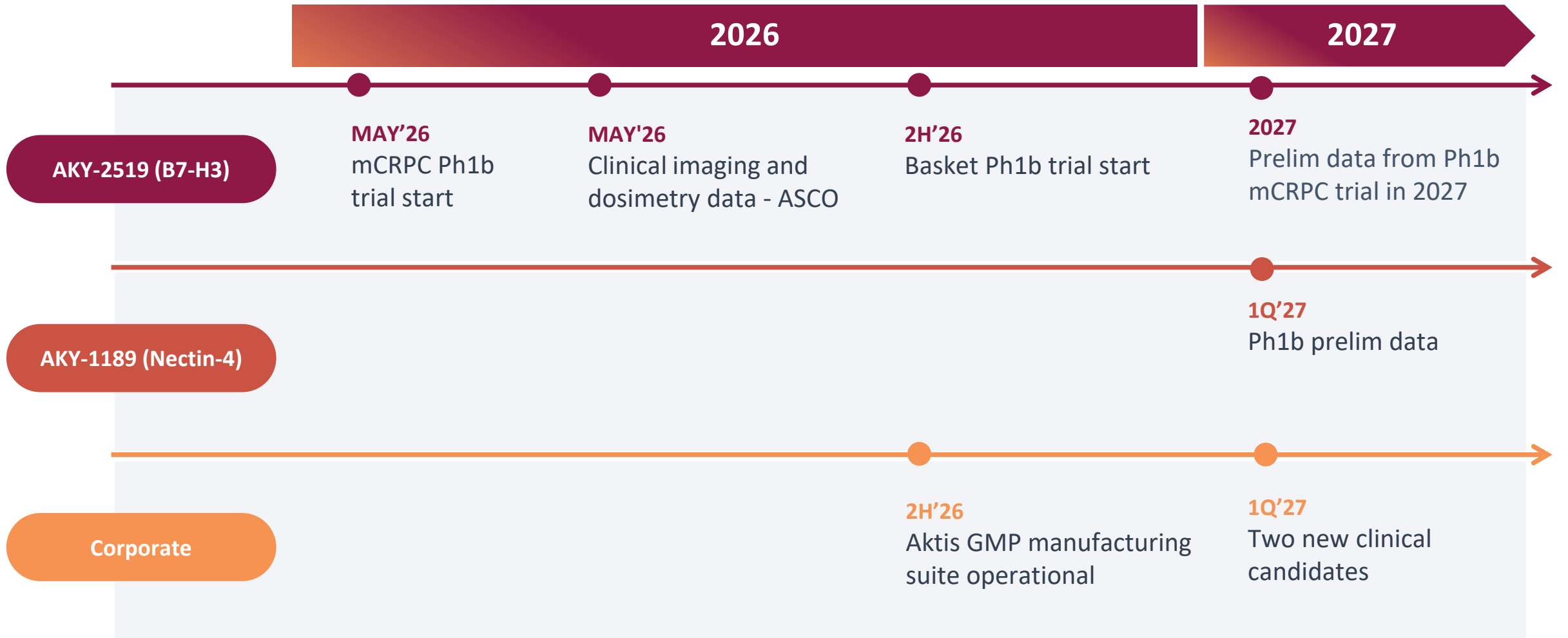
## **First-in-human PET/CT imaging with <sup>68</sup>Ga-AKY-2519, a B7-H3 targeted miniprotein radioconjugate, to demonstrate tumor uptake and normal tissue exposure across various advanced solid tumors\*\***

**DATE AND TIME:** May 30, 1:30 p.m. - 4:30 p.m. CDT

**PRESENTER:** Josephine Enste, Department of Nuclear Medicine, University of Duisburg-Essen, and German Cancer Consortium (DKTK)

PET/CT uptake in multiple tumor types **provides basis for the Phase 1b basket trial** for lung, colorectal, and other solid tumor cancers

# Multiple anticipated milestones over the next 12 months

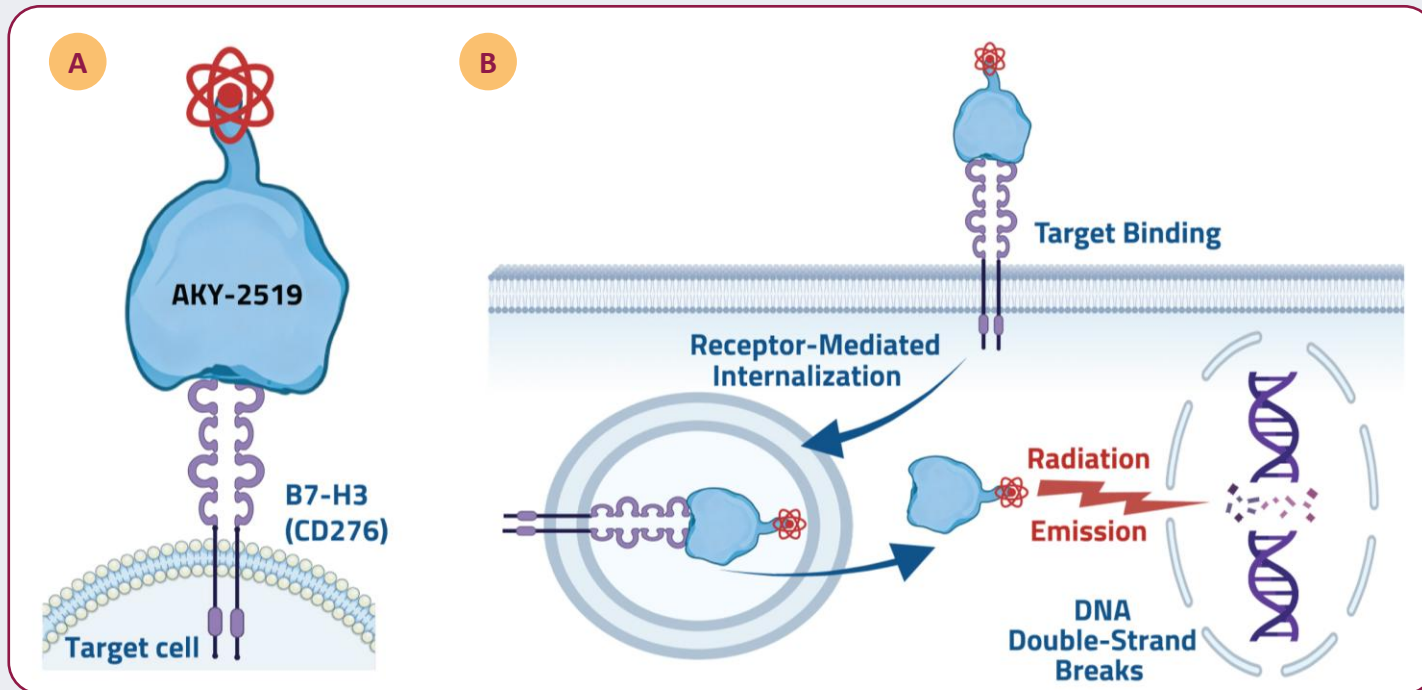




# **B7-H3 Overview & AKY-2519 Clinical Imaging and Dosimetry Data**

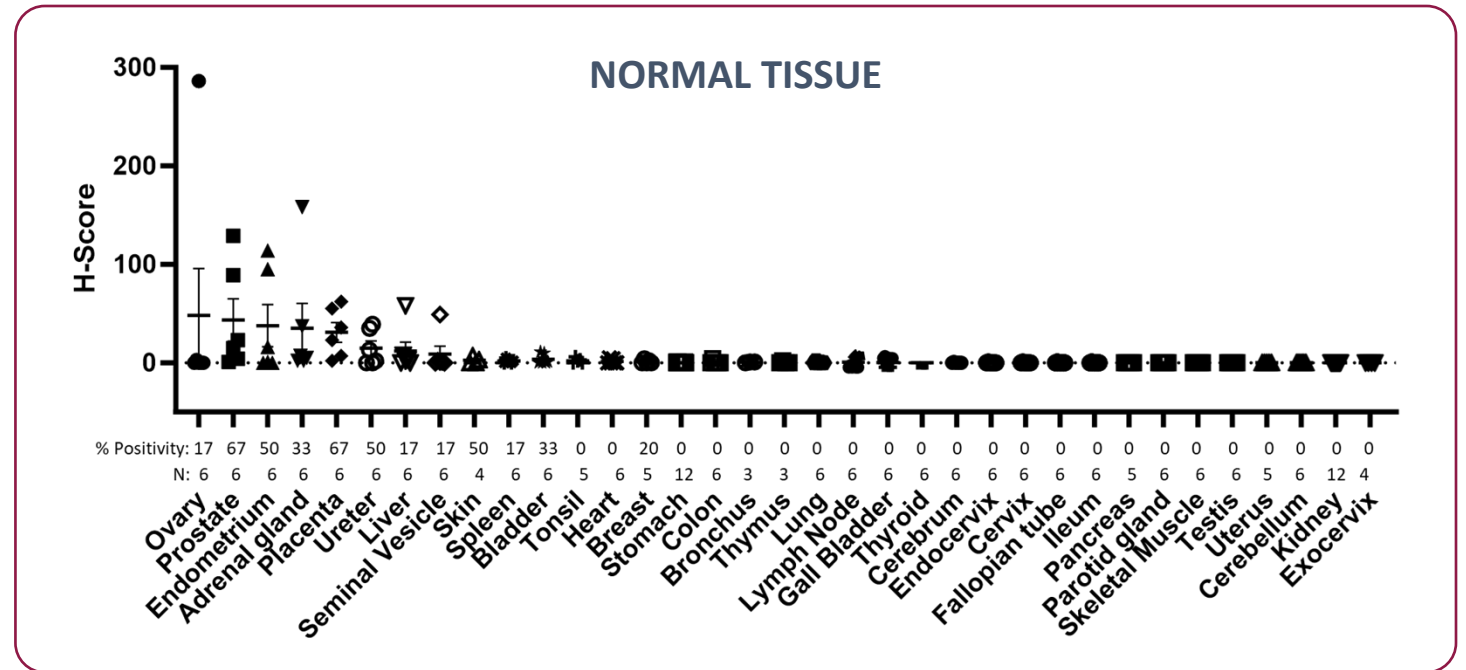
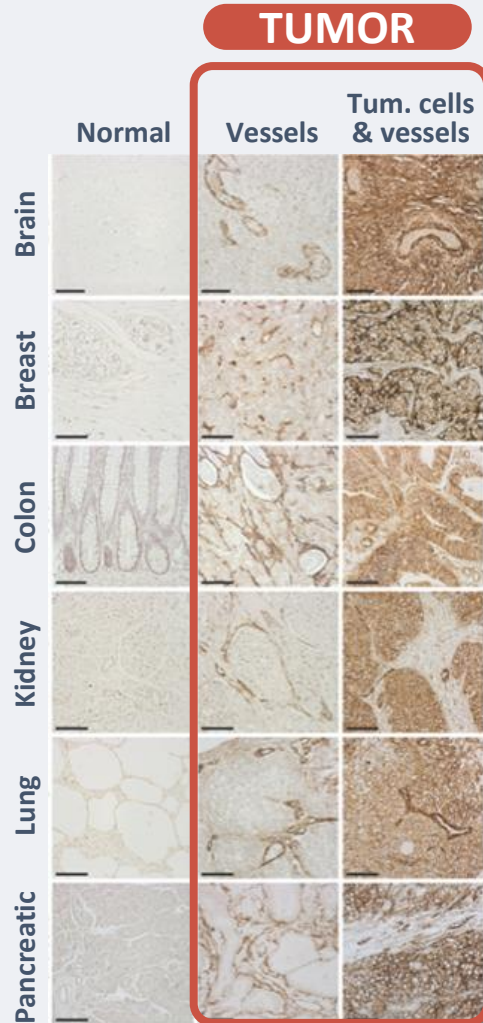
# AKY-2519 is a novel miniprotein radioconjugate designed to target B7-H3 Expressing Tumors

[<sup>225</sup>Ac]Ac-AKY-2519 RCT binds to B7-H3 on tumor cells (A) and results in cell death through radioactive decay (B)



- High affinity binding to B7-H3 ( $K_D = 0.45 \pm 0.17$  nM)
- Selective B7-H3 binding with no off-target binding when assessing 6,500+ surface proteins
- No-observed-adverse-effect level (NOAEL) based on 500x allometrically scaled human dose

# B7-H3 is a clinically-validated high-potential multi-tumor target



- B7-H3 is highly expressed in various solid tumors, including mCRPC, lung cancer and breast cancer, and shows minimal expression in normal organs<sup>1</sup>
- High expression has been associated with poor overall survival in RCC<sup>2</sup>, ESCC<sup>3</sup>, OC, PC, NSCLC and other tumor types<sup>4</sup>
- High expression is correlated with non-responsiveness to anti-PD-1 Tx in NSCLC<sup>5,6</sup>

# Key takeaways from the clinical imaging and dosimetry data for AKY-2519

**AKY-2519 was generally well tolerated**, with no reported adverse events or infusion-related reactions

Observed robust tumor doses paired with low predicted doses to critical normal tissues, suggest a **wide therapeutic index for therapy with actinium-225 in mCRPC**

**Low predicted dose to salivary glands** may differentiate AKY-2519 from PSMA-targeted agents

PET-CT imaging analyses using **AKY-2519 consistently identifies lesions also identified by PSMA-11**

PET-CT imaging of **AKY-2519 shows tumor uptake and retention across multiple B7-H3 expressing solid tumors** including mCRPC, lung cancers and CRC

Results support **broad clinical development** of AKY-2519 in multiple tumors and **informed the design of ongoing Phase 1b clinical trial** in patients with mCRPC

# AKY-2519 Early Human Imaging Assessment Workflow

34 patients imaged across 2 academic sites in South Africa and Europe

16 patients with mCRPC at NuMeRI  
at Pretoria, South Africa

**[<sup>68</sup>Ga]Ga-AKY-2519**  
for PET/CT imaging  
at 30, 60, and 90–150 minutes

**[<sup>68</sup>Ga]Ga-PSMA11**  
PET/CT imaging at 60 minutes

- Evaluate normal tissue **distribution** of AKY-2519
- Tumor **uptake and concordance** to PSMA-11

**[<sup>177</sup>Lu]Lu-AKY-2519**  
for SPECT/CT imaging  
at 3, 24, and 144 hours  
*Low dose, non-therapeutic (~0.37–0.56GBq)*

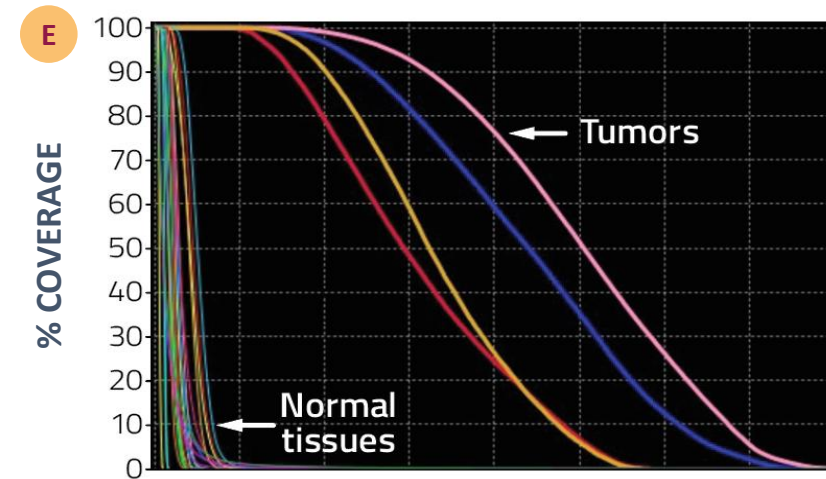
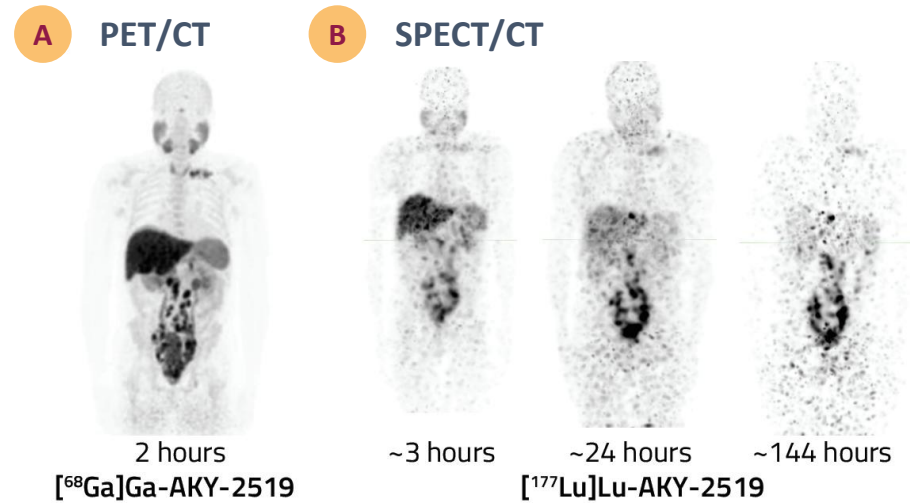
- **Dosimetry assessment** of normal tissues and tumors

18 patients with prostate, lung, colorectal, & other tumor types  
at University Hospital Essen, Essen, Germany

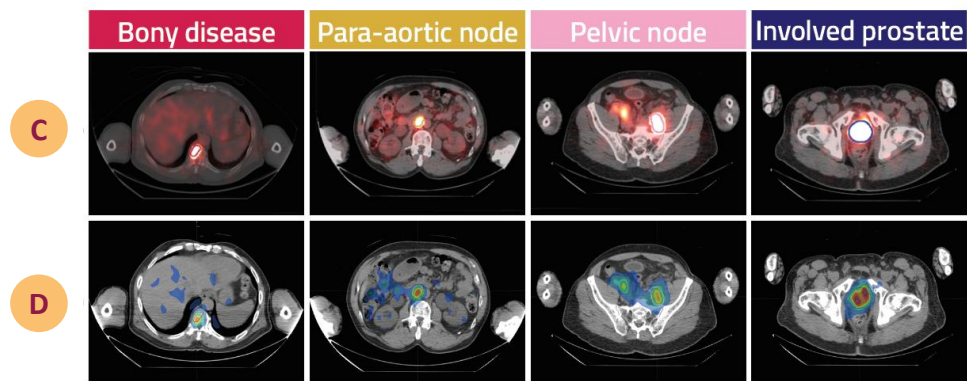
**[<sup>68</sup>Ga]Ga-AKY-2519** for PET/CT imaging  
at 15, 60, and 120 minutes

- Initial normal tissue **uptake**
- Tumor **uptake** across tumor types by SUV<sub>max</sub> and SUV<sub>mean</sub>

# AKY-2519 demonstrates robust tumor uptake and retention with predicted absorbed doses suggesting a wide therapeutic index



SECT/CT AXIAL IMAGES AT 24 HOURS



**F**

Region of Interest	Mean Absorbed Dose Coefficient ( $^{225}\text{Ac}$ ) $\text{Gy}_{\text{RBE}=5}/\text{MBq}$	Predicted Dose <sup>a</sup> at $\text{MBq} \times 4$ $\text{Gy}_{\text{RBE}=5}$
Involved prostate ± seminal vesicles	3.4 <sup>b</sup>	110
Bony disease	2.4 (4.5 with PVC)	75 (143 with PVC)
Para-aortic node	3.8 (7.5 with PVC)	122 (239 with PVC)
Pelvic node	4.8 <sup>b</sup>	155
<b>Normal Tissues</b>		
Kidney	0.29	9.2
Glands	0.11	3.6
Liver	0.26	8.2

# Administration of AKY-2519 was generally well tolerated and predicts normal tissue doses below established clinical benchmarks

## Predicted [<sup>225</sup>Ac]Ac-AKY-2519 absorbed doses in critical normal tissues

Normal Tissue (n=12) <sup>a</sup>	Mean Absorbed Dose Coefficient ( <sup>225</sup> Ac) Gy <sub>RBE=5</sub> /MBq (SD)	Predicted Absorbed Dose at 8 MBq x 4 Gy <sub>RBE=5</sub>
Bone marrow	0.04 (0.02)	1.3
Liver	0.31 (0.10)	9.9
Kidneys	0.50 (0.17)	16
Salivary glands	0.13 (0.04)	4.2

- Normal tissue dosimetry supportive of repeat dosing at clinically meaningful dose levels
- Low exposure to salivary glands differentiated from PSMA targeted therapies
- Profile supportive of therapeutic advancement of AKY-2519

# AKY-2519 demonstrates robust tumor uptake and retention with predicted absorbed doses suggesting a wide therapeutic index

- Predicted absorbed doses to selected tumors, including the involved prostate and seminal vesicles, as well as nodal and bony metastases, are within expected therapeutic ranges for approved radiopharmaceuticals.<sup>1</sup>

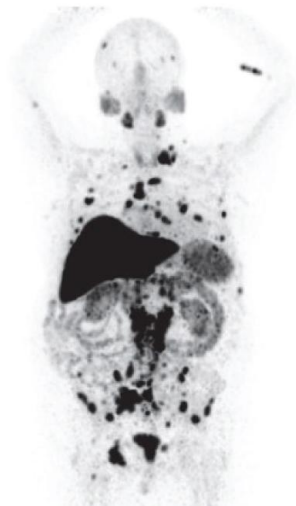
Estimated tumor absorbed doses of [<sup>225</sup>Ac]Ac-AKY-2519 in mCRPC lesions

Lesion Location	Evaluable Patients	Mean Absorbed Dose Coefficient <sup>a</sup> ( <sup>225</sup> Ac) Gy <sub>RBE=5</sub> /MBq (SD)	Mean Absorbed Dose Coefficient with PVC ( <sup>225</sup> Ac) Gy <sub>RBE=5</sub> /MBq (SD)	Predicted Absorbed Dose <sup>b</sup> at 8 MBq x 4 Gy <sub>RBE=5</sub> (SD)	Predicted Absorbed Dose <sup>b</sup> at 8 MBq x 4 with PVC Gy <sub>RBE=5</sub> (SD)
Involved prostate ± seminal vesicles	8	2.6 (1.2)	N/A <sup>c</sup>	83 (39)	N/A <sup>c</sup>
Nodal metastases	5	4.4 (2.8)	8.4 (4.2)	141 (88)	268 (134)
Bony metastases	6	1.5 (0.8)	3.8 (1.8)	48 (25)	121 (57)

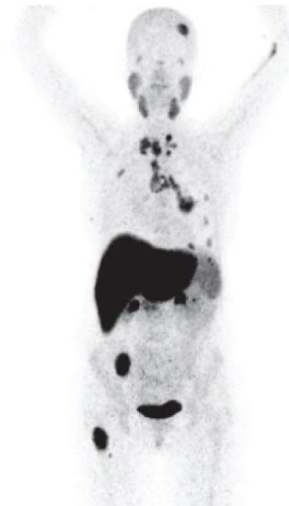
# [<sup>68</sup>Ga]Ga-AKY-2519 demonstrates robust tumor uptake in a variety of solid tumors

- Uptake of [<sup>68</sup>Ga]Ga-AKY-2519 was **observed across multiple tumor types** at various time points
- SUV<sub>max</sub> values for selected tumors **compares favorably** to those of approved radiopharmaceuticals<sup>1</sup>

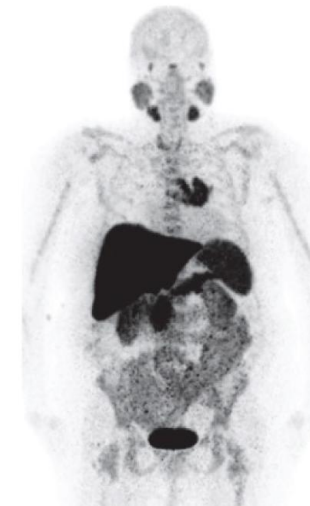
Representative patients across solid tumor types with robust tumor uptake at 120 minutes following [<sup>68</sup>Ga]Ga-AKY-2519 administration



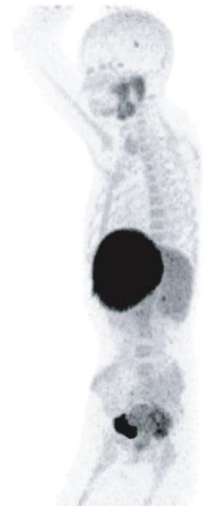
Prostate cancer  
SUV<sub>max</sub> = 33.9–37.4



NSCLC  
SUV<sub>max</sub> = 17.5–21.5



SCLC  
SUV<sub>max</sub> = 15.4



Rectal cancer  
SUV<sub>max</sub> = 15.3

# [<sup>68</sup>Ga]Ga-AKY-2519 uptake was consistently observed at high levels across metastatic disease sites in patients with prostate cancer

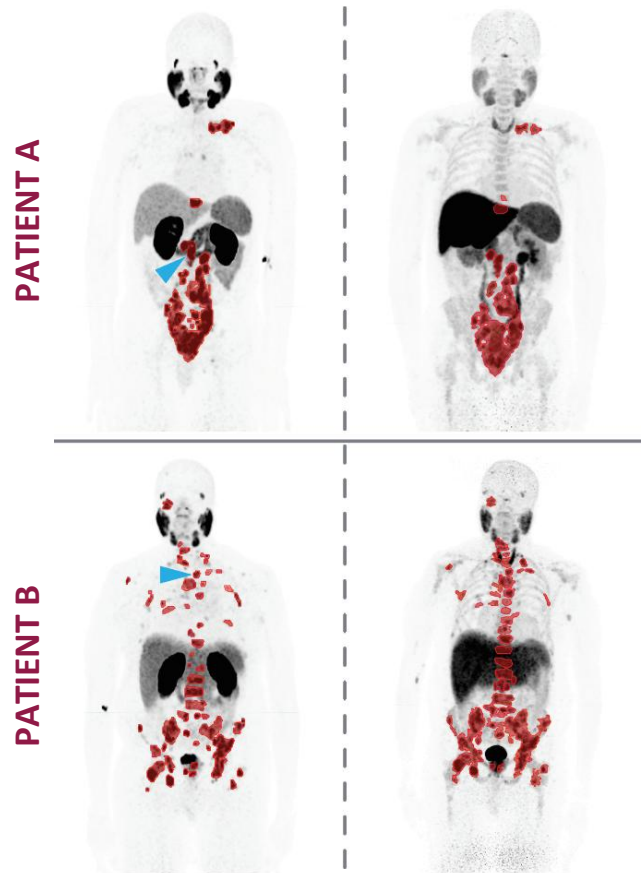
- Summary data was compiled for the largest cohort of patients (mHSPC/mCRPC) across multiple ROIs.
- Consistently high SUV values were observed across metastatic sites, with the most intense uptake observed in bone and visceral metastasis.

Uptake of [<sup>68</sup>Ga]Ga-AKY-2519 (120 min post infusion) in multiple metastatic disease sites from patients with prostate cancer (n=7)

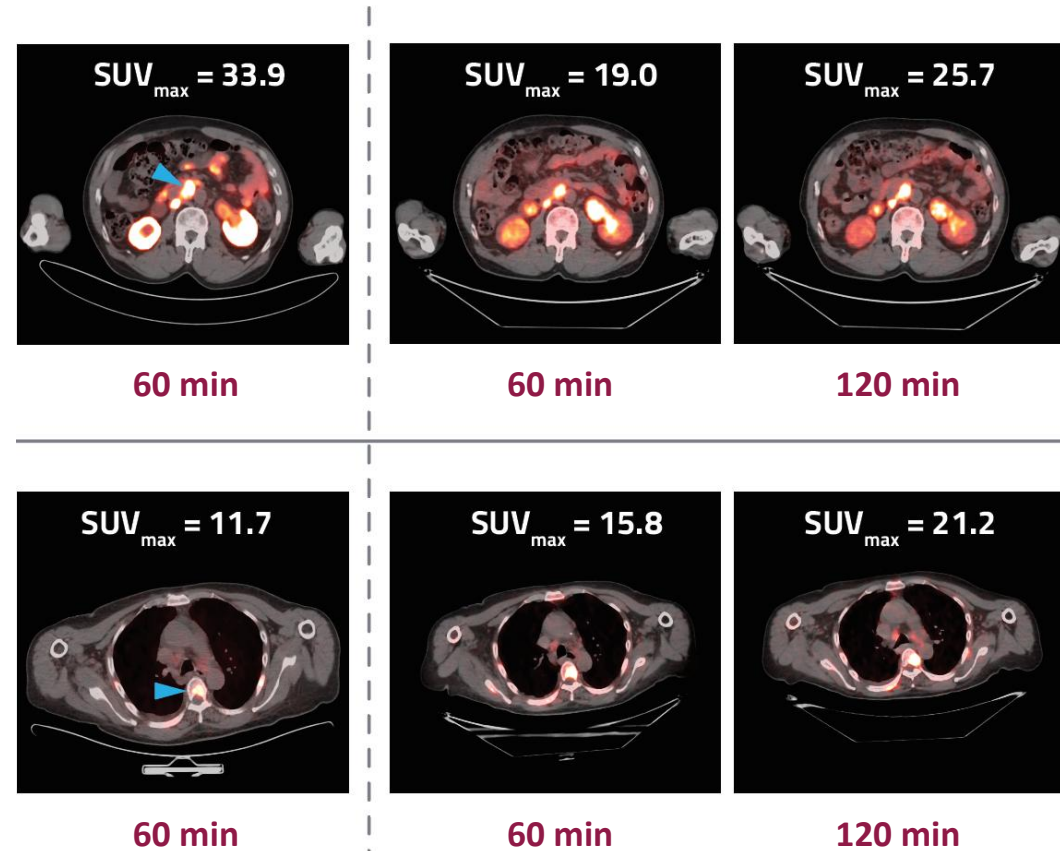
	Bone Metastases	Lymph Node Metastases	Visceral Metastases
<b>Median SUV<sub>max</sub></b>	40.4	13.8	31.0
<b>Median Suv<sub>peak</sub></b>	25.0	6.5	22.2
<b>Median SUV<sub>mean</sub></b>	16.1	5.1	18.7

# [<sup>68</sup>Ga]Ga-AKY-2519 consistently identifies lesions also identified by [<sup>68</sup>Ga]Ga-PSMA-11

**A** [<sup>68</sup>Ga]Ga-PSMA-11    [<sup>68</sup>Ga]Ga-AKY-2519



**B** [<sup>68</sup>Ga]Ga-PSMA-11    [<sup>68</sup>Ga]Ga-AKY-2519



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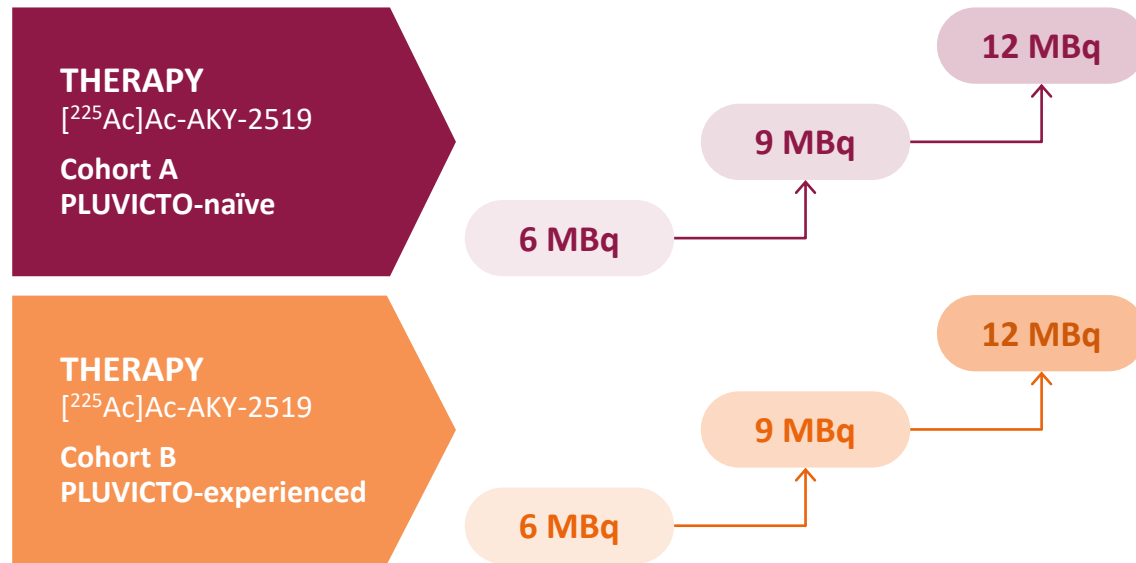
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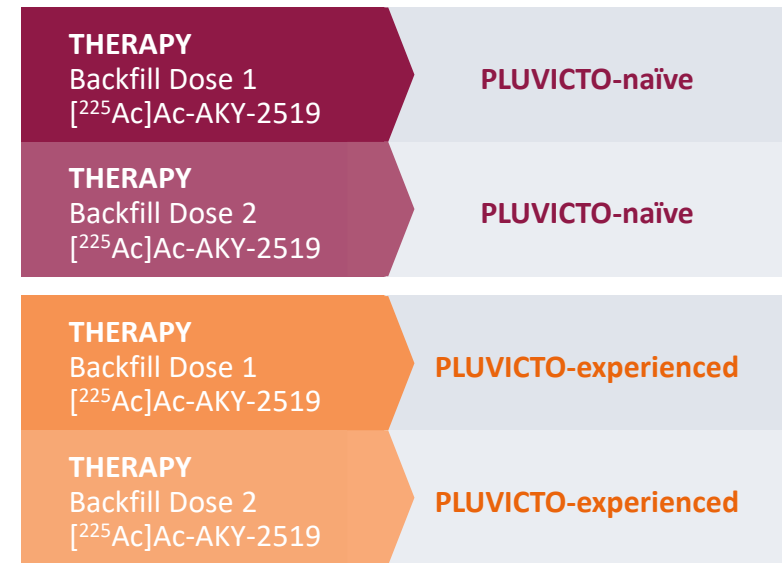
# Ongoing mCRPC-dedicated Phase 1b trial designed to rapidly generate data in PLUVICTO-naïve and -experienced patients

## AKY-2519-02 Trial design

### Dose escalation: BOIN



### Backfill ( $n \approx 30$ /cohort; escalation pts included)



*Dose levels for backfill may be different based on cohort*

All patients entering the study will have demonstrated tumor uptake following imaging with [64Cu]Cu-AKY-2519

# On track to initiate B7-H3 basket trial in 2H'26

## AKY-2519-02 Trial design

### PART 1

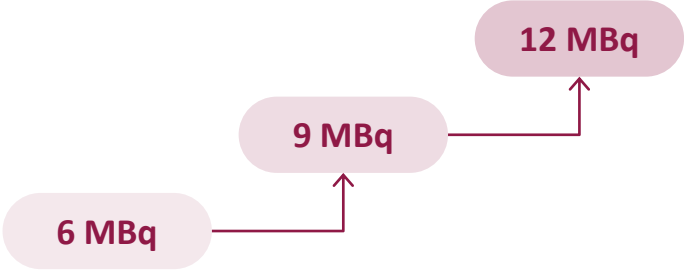
### PART 2

Dose escalation: BOIN (*n* = up to 18)

Backfill (*n* = up to 60)

Dose expansion (*n* = up to 70)

**THERAPY**  
[<sup>225</sup>Ac]Ac-AKY-2519



BACKFILL Dose 1	2L(+) NSCLC
	2L(+) Other
BACKFILL Dose 2	2L(+) NSCLC
	2L(+) Other

THERAPY [ <sup>225</sup> Ac]Ac-AKY-2519	Cohort 1 2L(+) NSCLC ( <i>n</i> =31)
THERAPY [ <sup>225</sup> Ac]Ac-AKY-2519	Cohort 2 Other solid tumors ( <i>n</i> =40)

All patients entering the study will have demonstrated tumor uptake following imaging with [<sup>64</sup>Cu]Cu-AKY-2519

# Fireside Chat



**Akos Czibere,**  
MD, Ph.D.

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**Chief Medical Officer**  
*Aktis Oncology*



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**Director**  
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**Timothy A. Yap,**  
MBBS, Ph.D.

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**Vice President and Head of Clinical Development,  
Therapeutics Discovery Division; Professor,  
Department of Investigational Cancer Therapeutics  
(Phase I Program)**  
*University of Texas MD Anderson Cancer Center*



**Thank You**