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# Canaccord Drug and Device Conference

October 2025



Dr Alan Taylor, Executive Chairperson

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## General

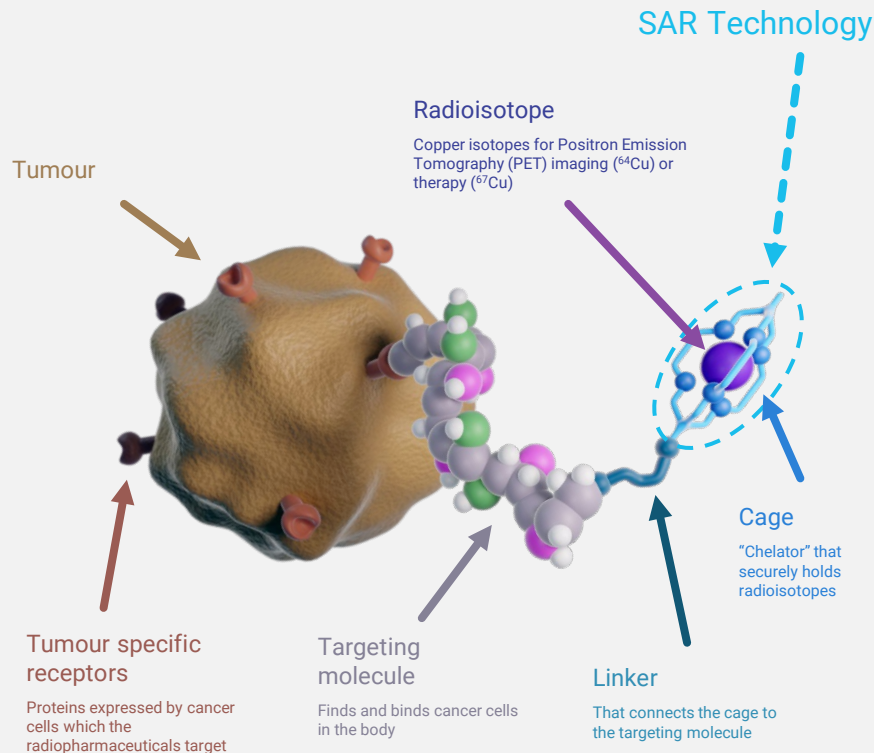
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# Clarity – The Copper Theranostics Company

Targeted Copper Theranostics are the next-generation disruptive platform in radiopharmaceuticals that employ the “perfect pairing” of copper-64 ( $^{64}\text{Cu}$ ) and copper-67 ( $^{67}\text{Cu}$ ) for diagnosis and therapy

## Proprietary SAR Technology enables Targeted Copper Theranostics

- Clarity’s SAR technology is a proprietary, highly specific and highly stable bifunctional cage (chelator) with a superior ability to retain copper isotopes within it and prevent their leakage into the body
- TCT deliver a compelling combination of high accuracy and high precision in the treatment of a range of cancers, as well as providing supply and logistical advantages over current theranostics



# SAR-bisPSMA

What's all the hype?

## Precision Targeting

Same product for imaging and therapy  
(<sup>64</sup>Cu/<sup>67</sup>Cu)

## Game changing treatment outcomes

Increased uptake & retention in lesions  
and detection of more & smaller lesions  
offer improved patient outcomes

## Optimised dosing

<sup>67</sup>Cu offers opportunity for higher  
dosing compared to competitors

## Broad impact in patient care

Remarkable efficacy and safety profile  
from first diagnosis to late-stage  
therapy

## Dual PSMA targeting

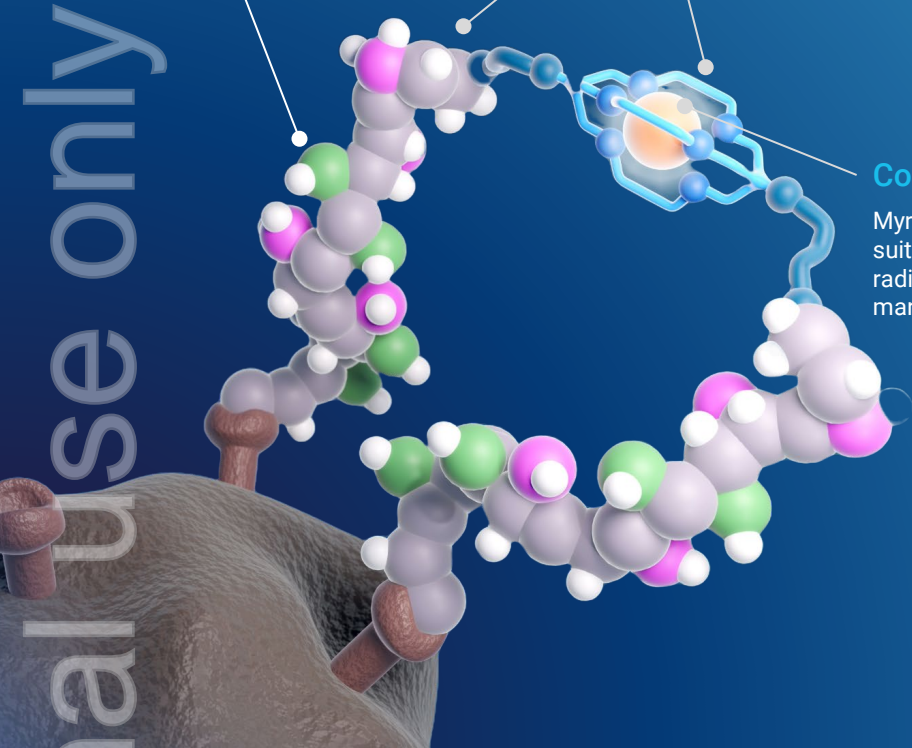
Unique dimer with two  
targeting molecules leads to  
increased tumour uptake  
and retention

## Two Proprietary Positions

1. Composition of matter on **chelator**  
that securely holds copper
2. Composition of matter on SAR-  
bisPSMA dual targeting molecule

## Copper isotopes

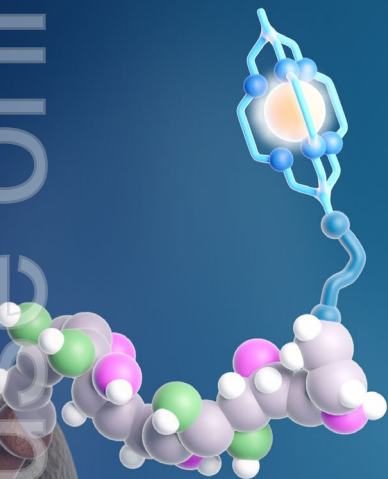
Myriad benefits ideally  
suited for today's  
radiopharmaceutical  
market



For professional use only

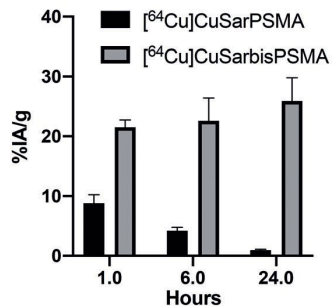
# Monomer

- Pluvicto®
- Pylarify®
- Posluma®
- $^{68}\text{Ga}$ -PSMA-11
- $^{177}\text{Lu}$ -PNT2002

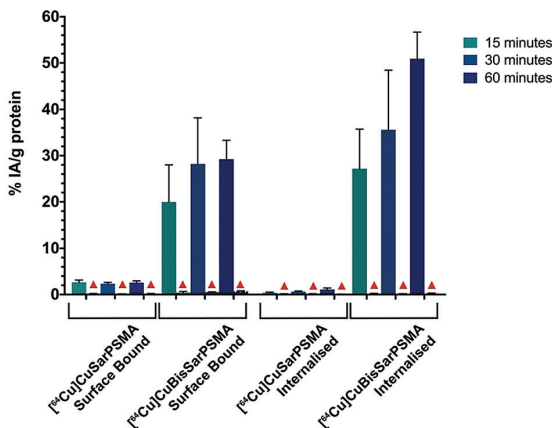


VS

Superior performance of bisPSMA compared to monomer PSMA

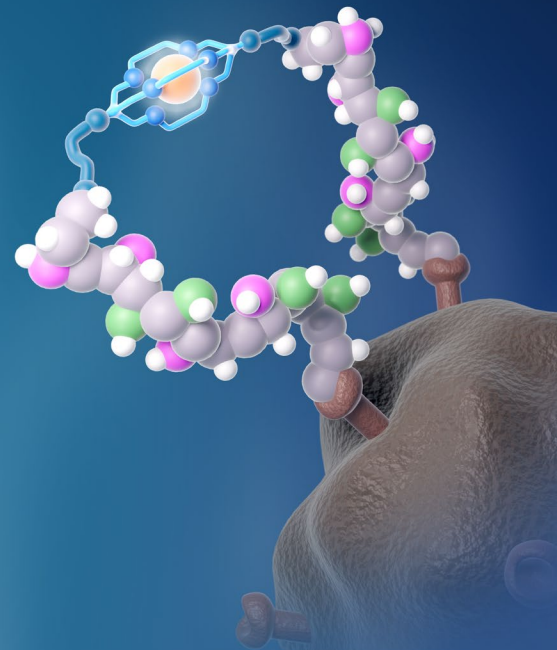


Significantly better binding and internalisation



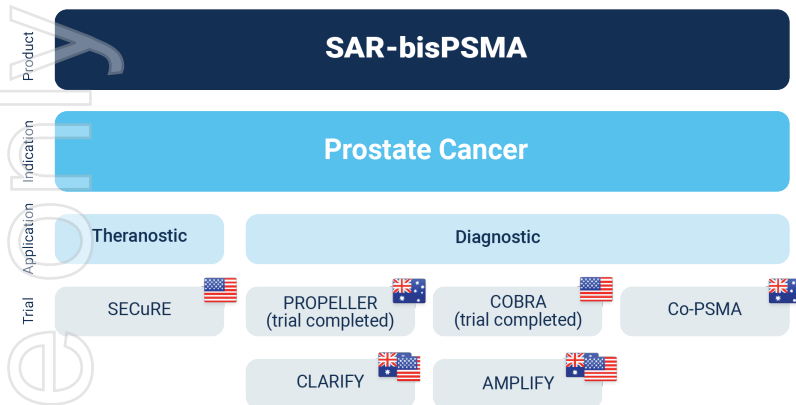
# Dimer

- SAR-bisPSMA



# SAR-bisPSMA

Targets the Prostate Specific Membrane Antigen (PSMA), present in the majority of prostate cancers



## SECURE - Phase I/IIa

SECURE

- Cohort Expansion (Phase II) ongoing at 8 GBq dose level (enzalutamide combination allowed)
- Dose Escalation (Phase I) successfully completed
- Fast-Track Designation granted by the U.S. FDA

## CLARIFY - Phase III

CLARIFY

- Registrational Phase III imaging trial of participants with high-risk prostate cancer prior to radical prostatectomy using  $^{64}\text{Cu}$ -SAR-bisPSMA
- Fast-Track Designation granted by the U.S. FDA
- Recruitment ongoing

## AMPLIFY - Phase III

AMPLIFY

- Registrational Phase III imaging trial with  $^{64}\text{Cu}$ -SAR-bisPSMA in prostate cancer patients with biochemical recurrence (BCR)
- Fast-Track Designation granted by the U.S. FDA
- Recruitment ongoing

## Co-PSMA - Phase II Investigator-Initiated Trial (IIT)

- Led by Prof Louise Emmett at St Vincent's Hospital Sydney
- Phase II head-to-head comparison of  $^{64}\text{Cu}$ -SAR-bisPSMA vs. standard-of-care  $^{68}\text{Ga}$ -PSMA-11 product for the detection of prostate cancer recurrence
- Recruitment completed; primary endpoint achieved

used



at

# Next-generation SAR-bisPSMA diagnostic is coming

Current PSMA PET imaging market for the US is approximately US\$2 billion per year. Improved lesion uptake and detection by  $^{64}\text{Cu}$ -SAR-bisPSMA aims to overcome the significant low sensitivity issues of first-generation PSMA PET agents and displace approved products.

Lantheus: PYLARIFY® ( $^{18}\text{F}$ -DCFPyL) US sales Q2 25: ~US\$251M  
 Telix: Illuccix® (generic PSMA-11 kit) US sales Q2 25: ~US\$154M

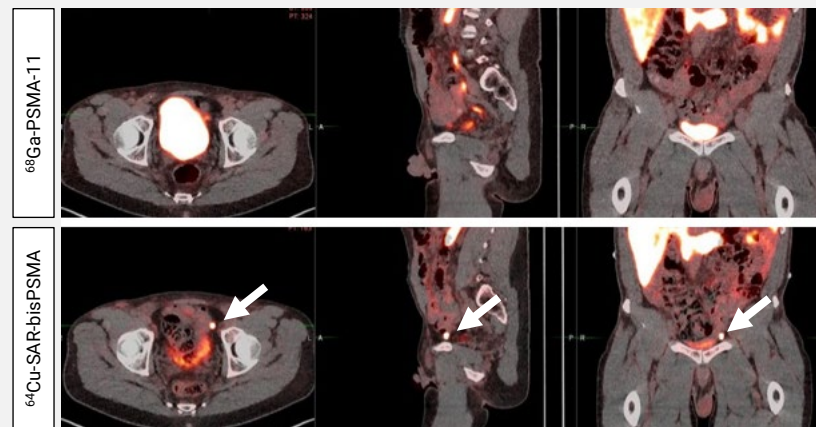
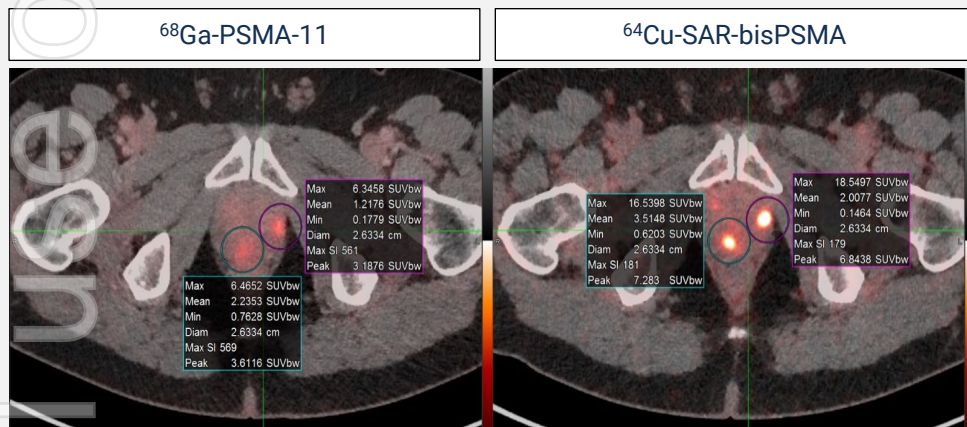


Specificity - High   
 Sensitivity - Low 

## $^{64}\text{Cu}$ -SAR-bisPSMA vs. $^{68}\text{Ga}$ -PSMA-11 – PROPELLER study (pre-prostatectomy)

2-3x more uptake and contrast

More lesions identified



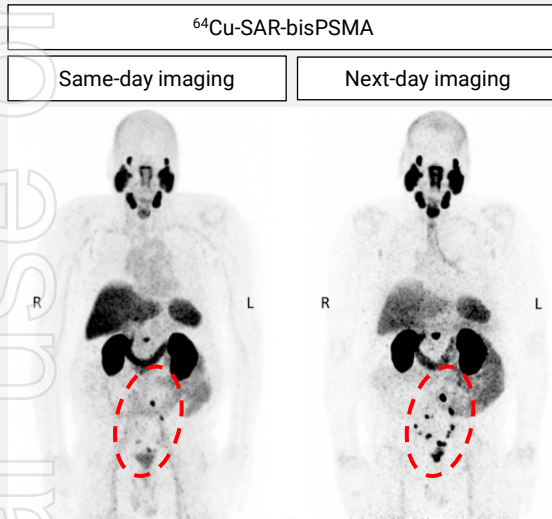
Left images: concordant lesions (same patient). SUVmax, SUVmean, tumour-to-background ratio: 2-3x increased values in  $^{64}\text{Cu}$ -SAR-bisPSMA vs.  $^{68}\text{Ga}$ -PSMA-11 PET ( $p < 0.001$ ). Right images: pelvic lymph node identified by  $^{64}\text{Cu}$ -SAR-bisPSMA but not by  $^{68}\text{Ga}$ -PSMA-11 (PC confirmed by histopathology). Lengyelova & Emmett et al. PROPELLER study. ASCO, 2023.

# SAR-bisPSMA is safe and effective in detecting tumours in prostate cancer patients

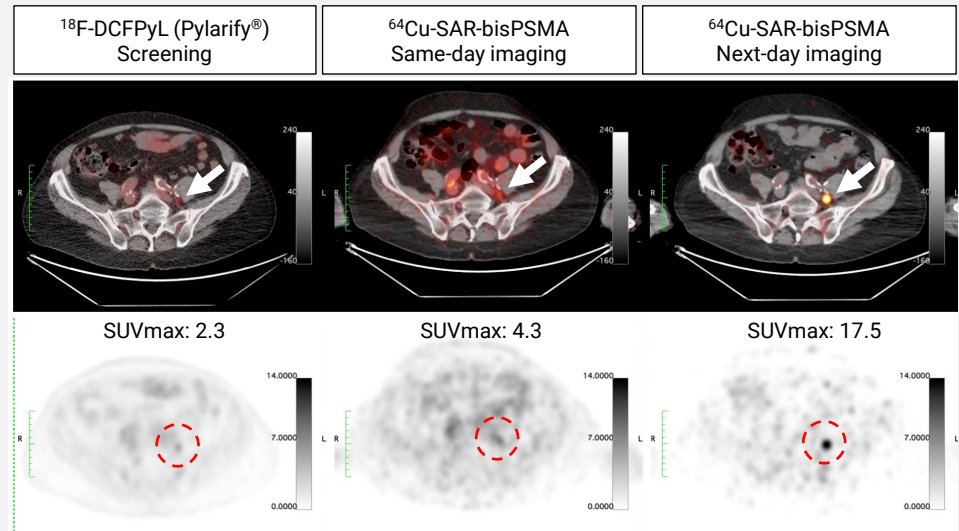
Clinicians reported they would change their treatment plan in approximately 50% of patients due to  $^{64}\text{Cu}$ -SAR-bisPSMA scans, signalling a potential material improvement in patient care

## Patients with negative/equivocal SOC scans - COBRA study (biochemical recurrence)

**82%** more lesions detected on next-day imaging (2 mm-range)



**34%** more patients with a positive scan on next-day imaging



Left images. Up to 80 lesions detected on same-day imaging vs. up to 153 lesions on next-day imaging across all participants. Right images: pelvic lymph node detected by  $^{64}\text{Cu}$ -SAR-bisPSMA on next-day imaging, but not with Pylarify® at screening. Patients with a positive  $^{64}\text{Cu}$ -SAR-bisPSMA scan: from up to 58% to up to 80%, same and next-day imaging respectively). Nordquist et al., SNMMI 2024.

# Higher uptake and contrast in lesions on next-day imaging and detection of lesions in the 2-mm range

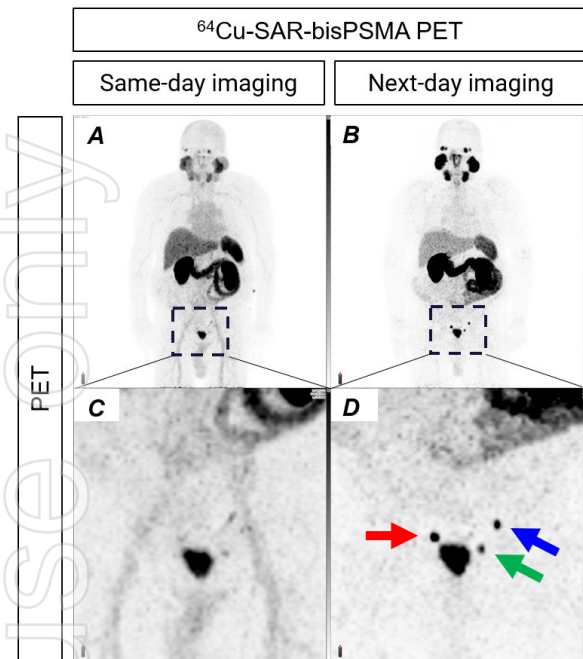
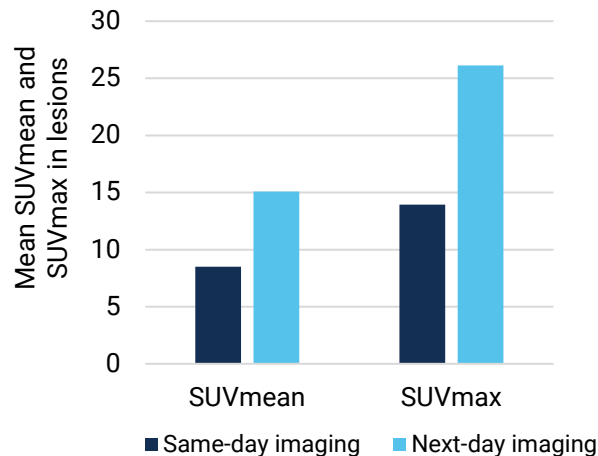


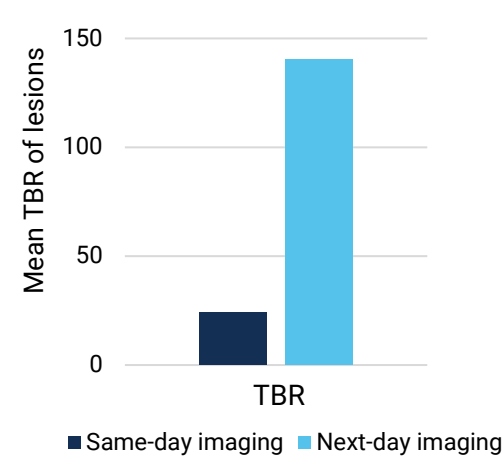
Figure 1. Pelvic lymph nodes showing uptake of  $^{64}\text{Cu}$ -SAR-bisPSMA on next-day imaging (arrows, B and D). Blue arrow: lesion size 3.8 mm x 4.4 mm, SUVmean 20.6, SUVmax 22.1 and TBR 130.1. Green arrow: lesion size also 3.8 mm x 4.4 mm, SUVmean 11.9, SUVmax 12.8 and TBR 75.3. Red arrow: size >5 mm. Inset in top images (A, B) displays pelvic region (bottom images, C and D).

## SUVmean and SUVmax in lesions detected by $^{64}\text{Cu}$ -SAR-bisPSMA



**>80% increase** in mean SUVmean and SUVmax (same-day vs. next-day imaging)

## TBR of lesions detected by $^{64}\text{Cu}$ -SAR-bisPSMA

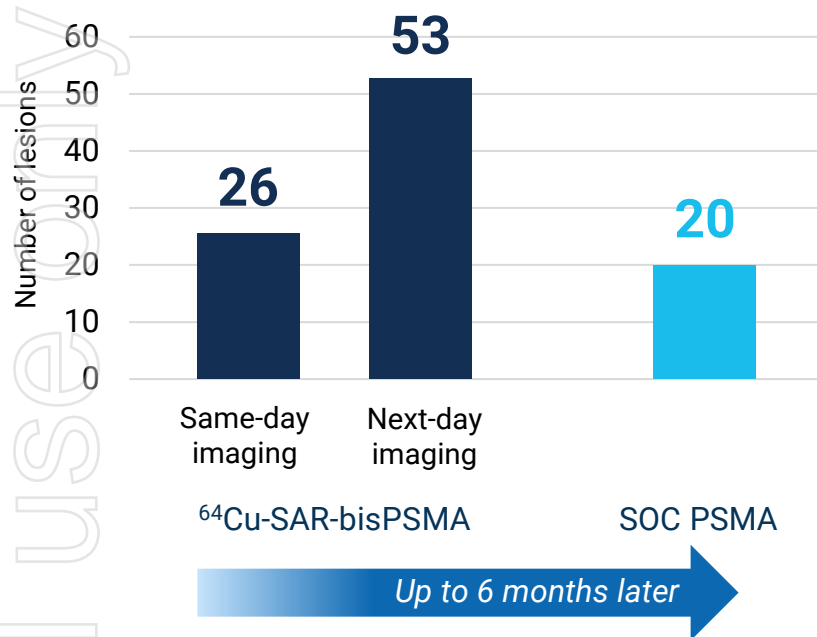


**>5x higher** mean TBR (same-day vs. next-day imaging)

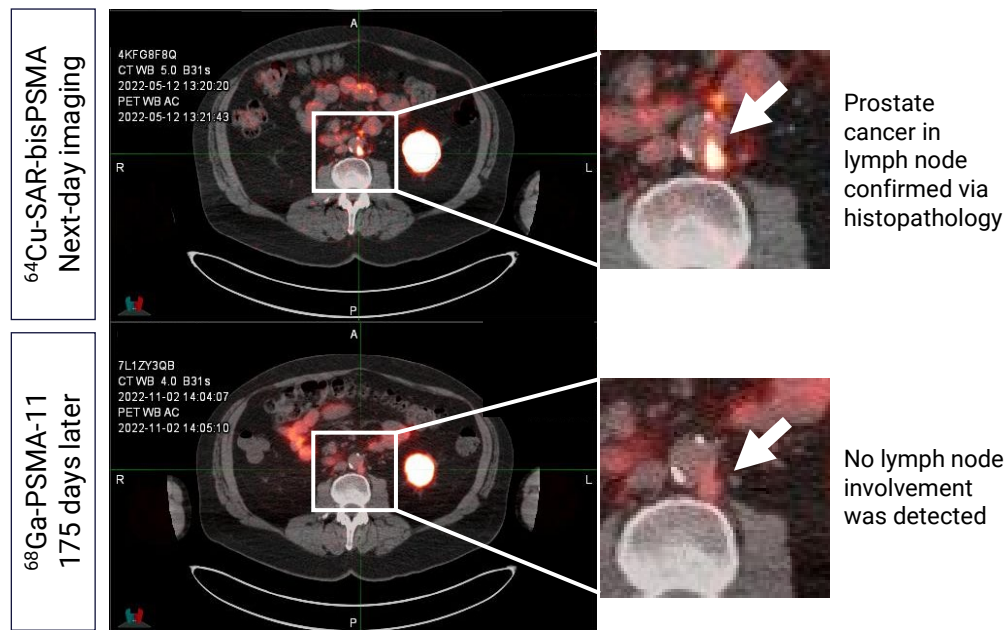
Figure 2. SUVmean/max and TBR comparing same-day (Day 0) and next-day (Day 1) imaging. Average increase across 3 readers. SUVmean: mean standardised uptake value. SUVmax: maximum standardised uptake value. TBR: tumour-to-background ratio. The SUVmax, SUVmean and TBR were assessed in up to 25 lesions per patient on each  $^{64}\text{Cu}$ -SAR-bisPSMA scan. Ranges across the readers for same-day and next-day imaging, respectively: SUVmean 6.6-9.9 and 14.7-15.8; SUVmax 13.9-14.0 and 22.2-33.4; TBR 23.2-25.4 and 118.1-181.7. TBR = SUVmax of the lesions / SUVmean of the gluteus region.

# $^{64}\text{Cu}$ -SAR-bisPSMA identifies lesions months before currently approved PSMA PET agents

Number of lesions identified by  $^{64}\text{Cu}$ -SAR-bisPSMA and SOC PSMA agents

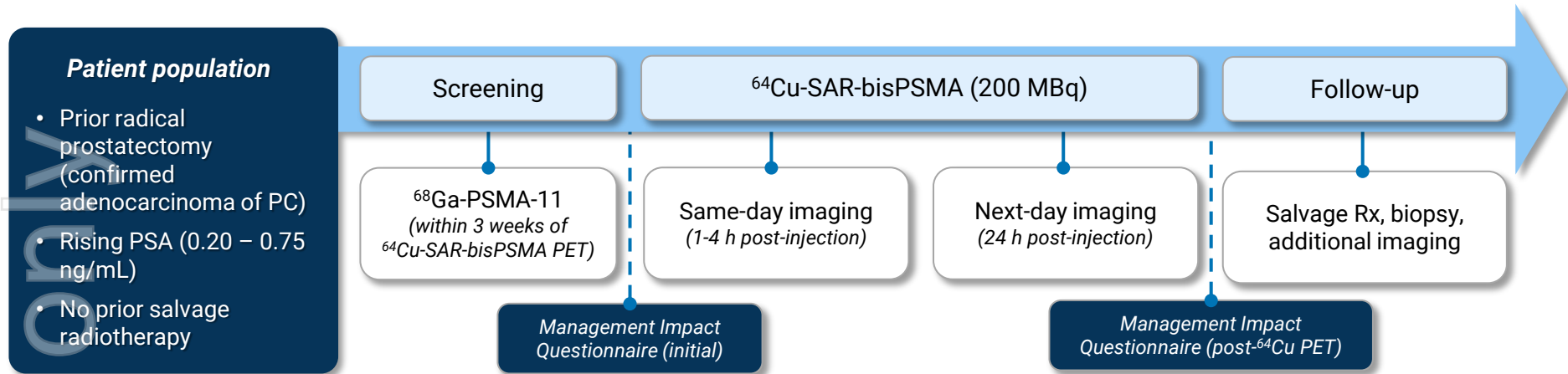


$^{64}\text{Cu}$ -SAR-bisPSMA detects lymph node missed by  $^{68}\text{Ga}$ -PSMA-11 (SOC PET performed ~6 months later)



Graph: Average number of lesions identified by the readers on same-day, next-day imaging ( $^{64}\text{Cu}$ -SAR-bisPSMA) or standard of care (SOC) PSMA PET ( $^{68}\text{Ga}$ -PSMA-11 or  $^{18}\text{F}$ -DCFPyL) in a subset of 20 participants with follow-up SOC PSMA PET: 26.3, 52.7 and 20, respectively. Median number of days between Day 0 and the follow-up SOC scan: 73.5 (range 29-180). Images: retroperitoneal lesion detected by  $^{64}\text{Cu}$ -SAR-bisPSMA on next-day imaging (confirmed by all 3 readers).  $^{68}\text{Ga}$ -PSMA-11 scan performed 176 days post-Day 0 (175 days post-Day 1) did not show uptake of tracer. PET/CT fusion.

# Co-PSMA IIT achieves primary endpoint: Head-to-head trial of $^{64}\text{Cu}$ -SAR-bisPSMA vs. $^{68}\text{Ga}$ -PSMA-11 in low-PSA BCR



*The Co-PSMA trial has successfully met its primary endpoint, demonstrating that  $^{64}\text{Cu}$ -SAR-bisPSMA PET/CT detects significantly more lesions per patient vs. SOC  $^{68}\text{Ga}$ -PSMA-11 PET/CT in BCR patients with low PSA*

# Thank you

## Contact details

**Dr Alan Taylor**

Executive Chairperson

E: [alan.taylor@claritypharm.com](mailto:alan.taylor@claritypharm.com)

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