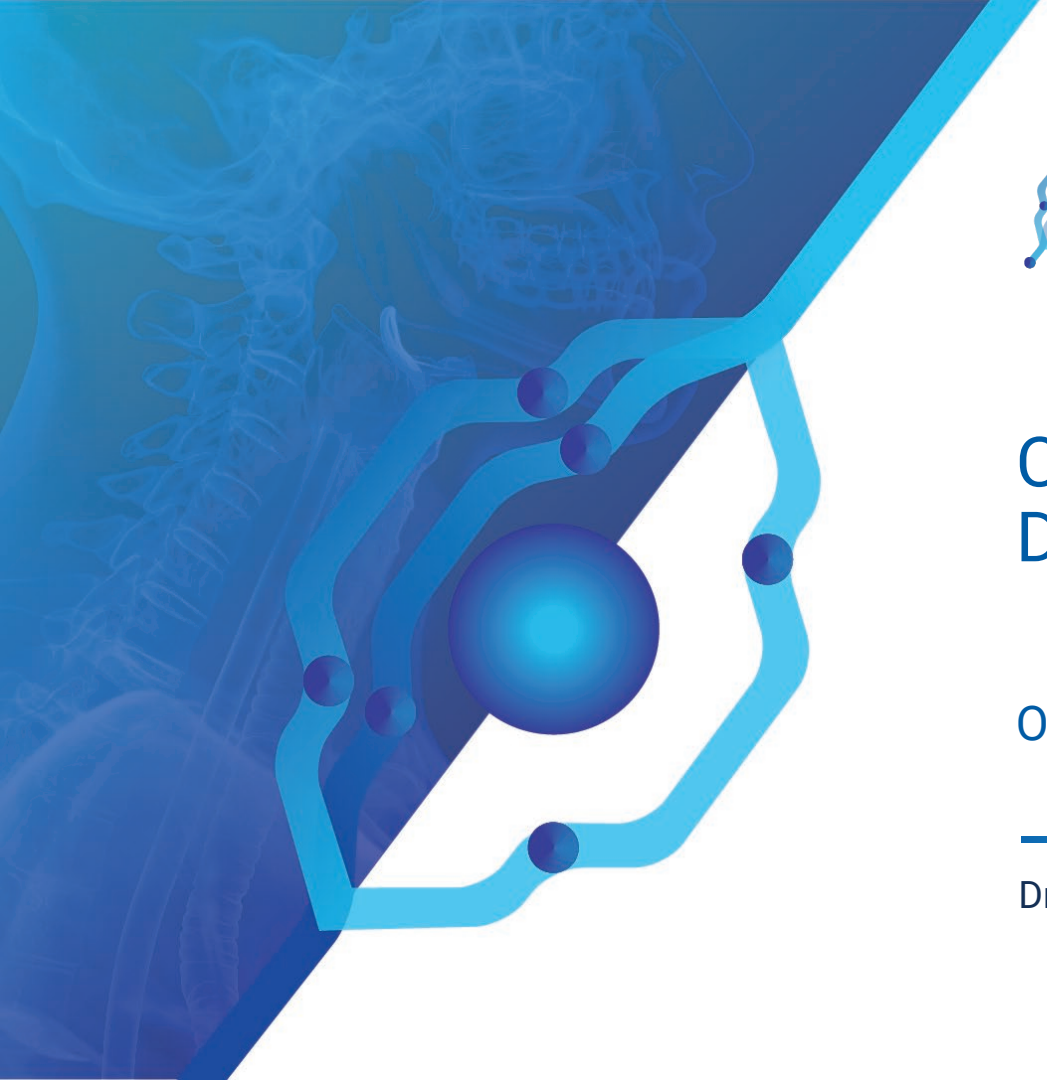

CLARITY
PHARMACEUTICALS

# Canaccord Drug and Device Conference

October 2025

Dr Alan Taylor, Executive Chairperson

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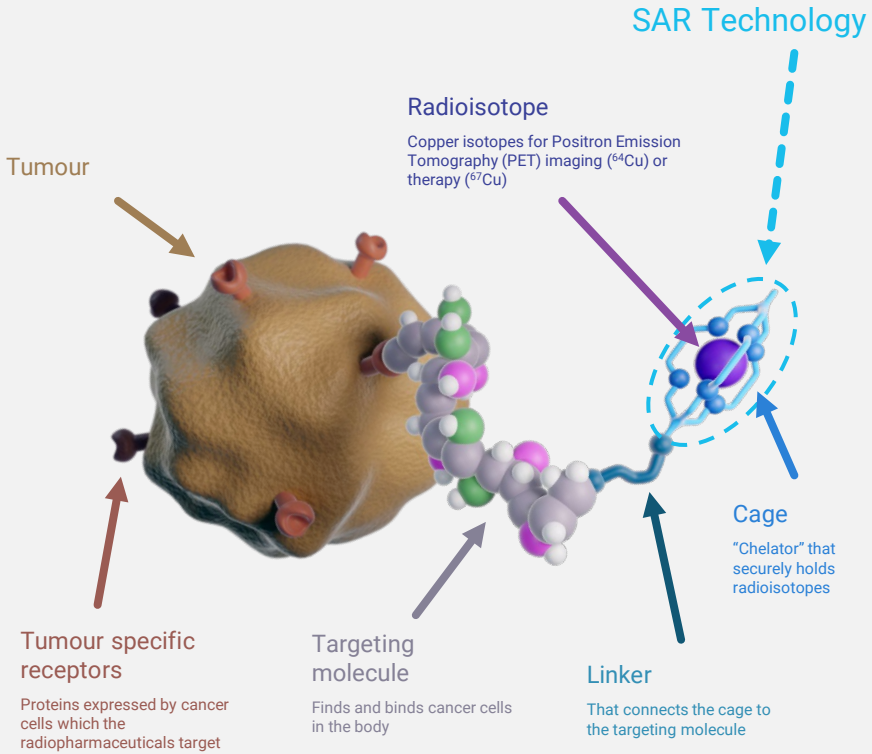
# Clarity – The Copper Theranostics Company

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

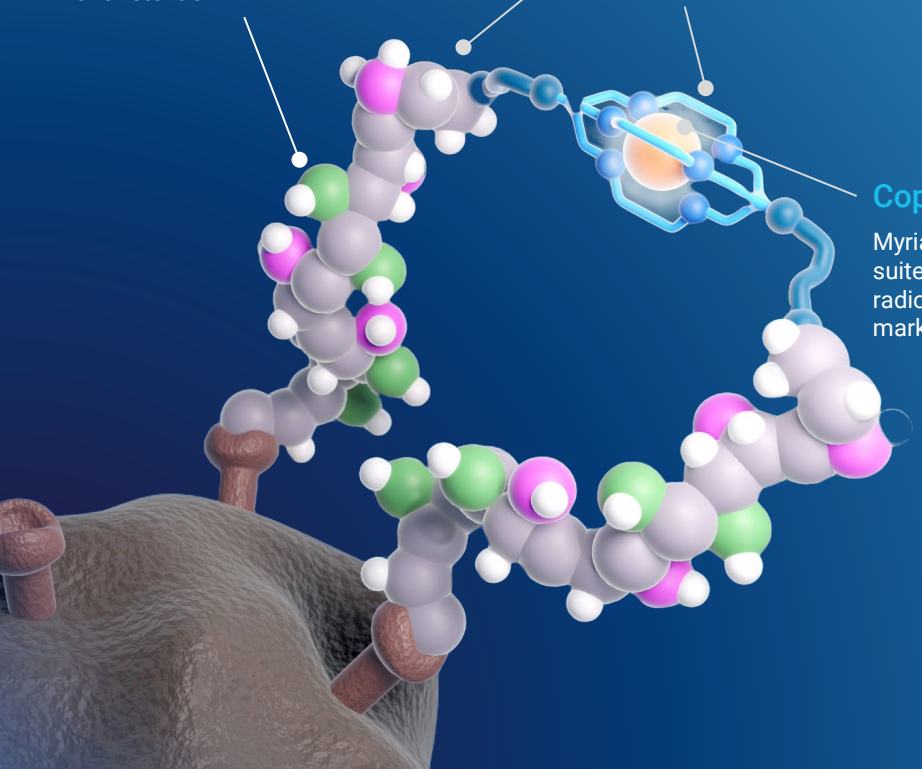
## What's all the hype?

### 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

### Precision Targeting

Same product for imaging and therapy ($^{64}$Cu/$^{67}$Cu)

### Game changing treatment outcomes

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

### Optimised dosing

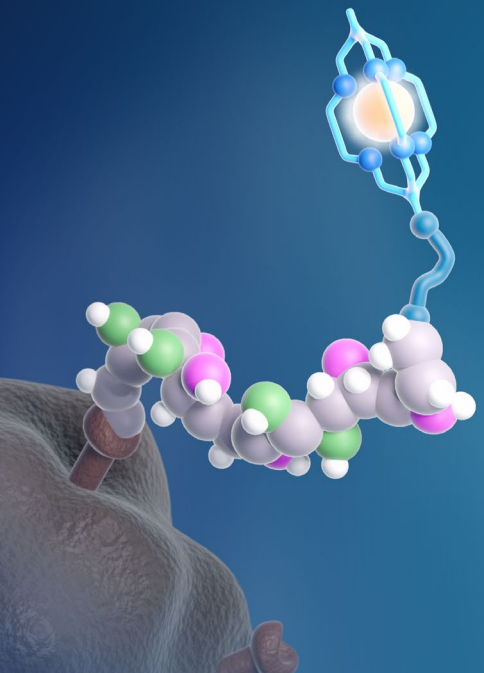
$^{67}$Cu offers opportunity for higher dosing compared to competitors

### Broad impact in patient care

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

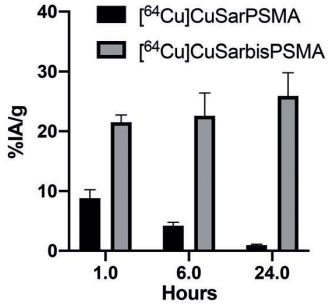
# Monomer

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

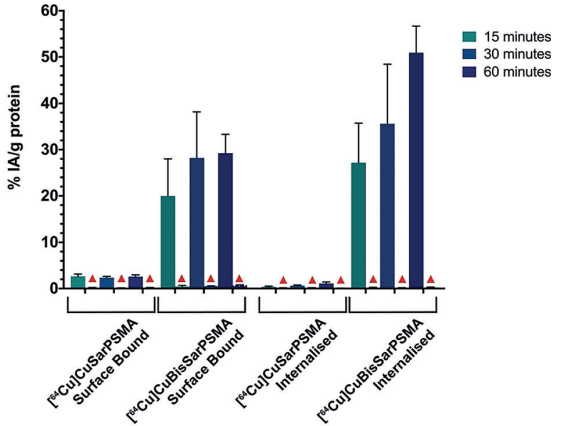


# vs

## Superior performance of bisPSMA compared to monomer PSMA



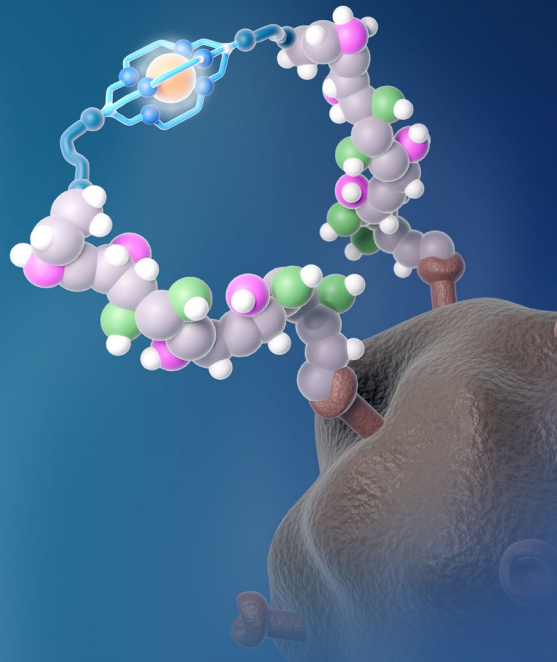

## Significantly better binding and internalisation




*Zia et al., 2019. Ang.Chem*

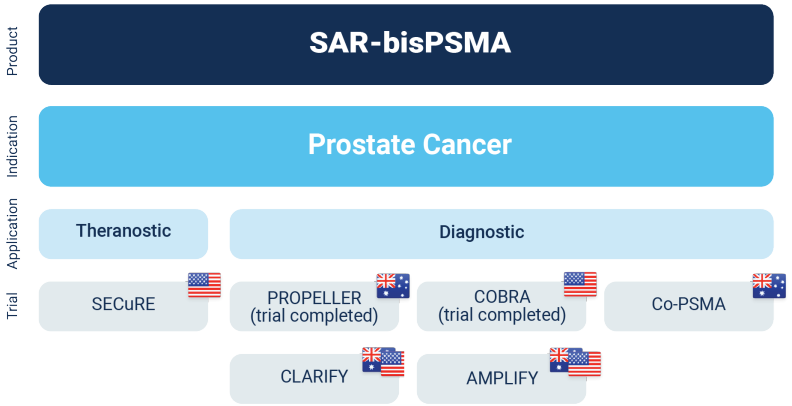
# Dimer

- SAR-bisPSMA



# SAR-bisPSMA

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




SECuRE - Phase I/IIa

- 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

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

AMPLIFY – Phase III

- Registrational Phase III imaging trial with $^{64}$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 $^{64}$Cu-SAR-bisPSMA vs. standard-of-care $^{68}$Ga-PSMA-11 product for the detection of prostate cancer recurrence
- Recruitment completed; primary endpoint achieved

# 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 $^{64}$Cu-SAR-bisPSMA aims to overcome the significant low sensitivity issues of first-generation PSMA PET agents and displace approved products.

Lantheus: PYLARIFY® ($^{18}$F-DCFPyL) US sales Q2 25: ~US$251M

Telix: Illuccix ® (generic PSMA-11 kit) US sales Q2 25: ~ US$154M

→

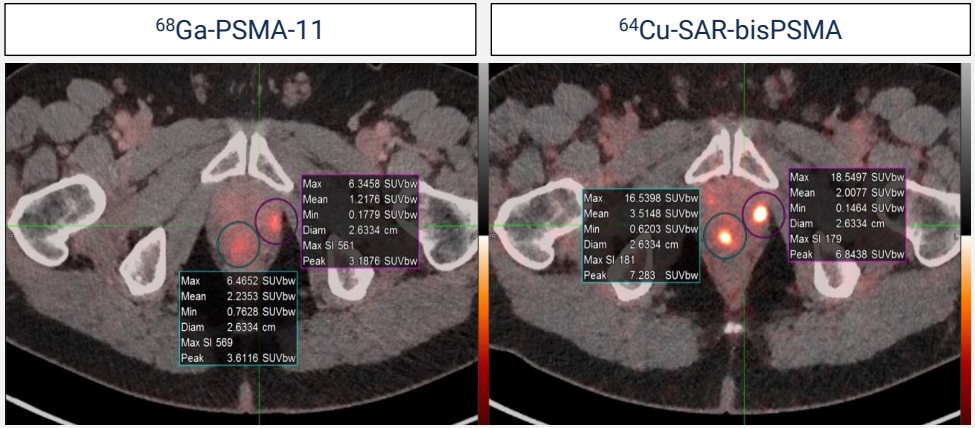
Specificity - High ✓

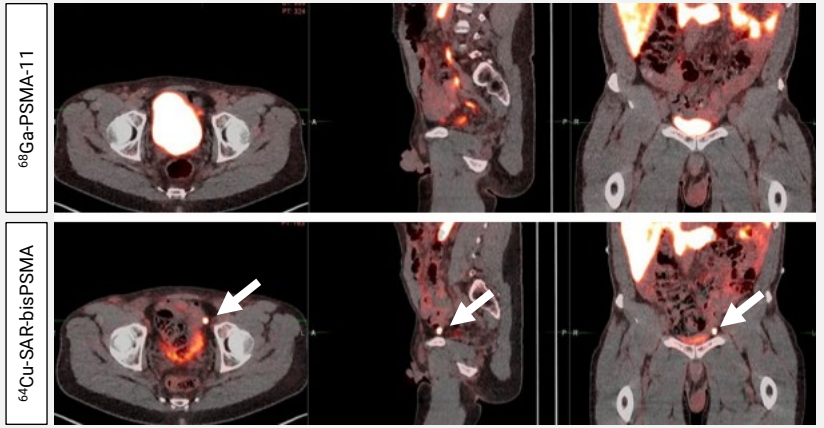
Sensitivity - Low ✗

## $^{64}$Cu-SAR-bisPSMA vs. $^{68}$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 $^{64}$Cu-SAR-bisPSMA vs. $^{68}$Ga-PSMA-11 PET (p<0.001). Right images: pelvic lymph node identified by $^{64}$Cu-SAR-bisPSMA but not by $^{68}$Ga-PSMA-11 (PC confirmed by histopathology). Lengyelova & Emmett et al. PROPELLER study. ASCO, 2023.

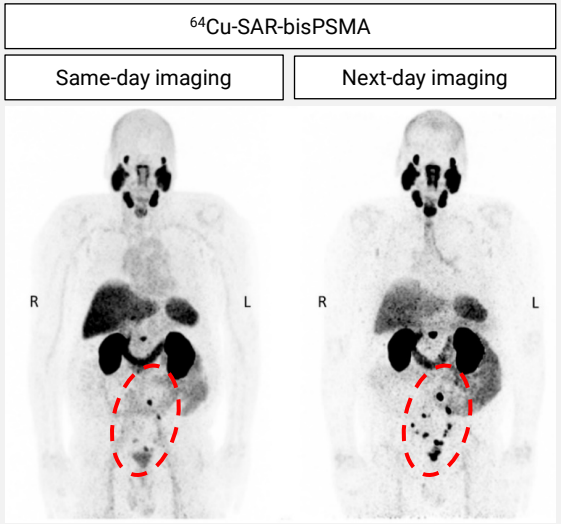
# SAR-bisPSMA is safe and effective in detecting tumours in prostate cancer patients

COBRA

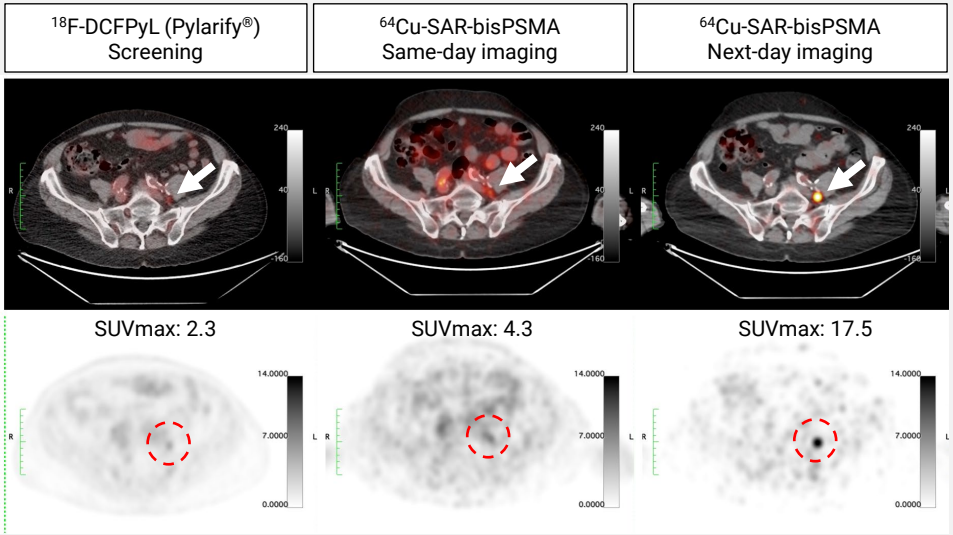
Clinicians reported they would change their treatment plan in approximately 50% of patients due to $^{64}$Cu-SAR-bisPSMA scans, signalling a potential material improvement in patient care

## 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

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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 $^{64}$Cu-SAR-bisPSMA on next-day imaging, but not with Pylarify® at screening. Patients with a positive $^{64}$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

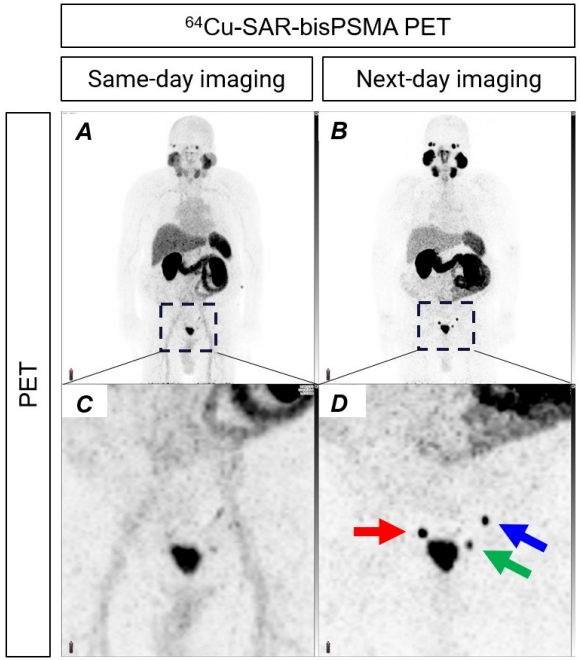
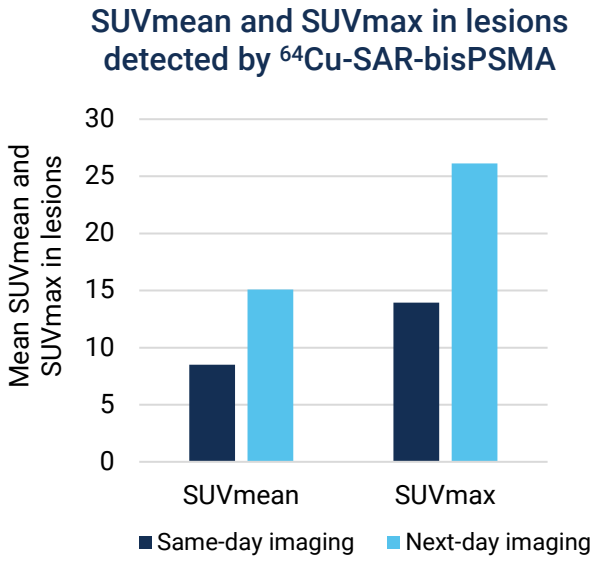
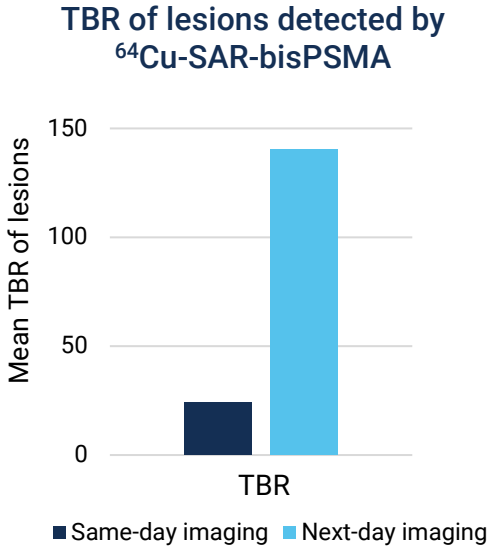



Figure 1. Pelvic lymph nodes showing uptake of $^{64}$Cu-SAR-bisPSMA on next-day imaging (arrows, B and D). Blue arrow: lesion size 3.8 mm x 4.4 mm, SUVmean 20.6, SUVmax 22.1 and TBR 130.1. Green arrow: lesion size also 3.8 mm x 4.4 mm, SUVmean 11.9, SUVmax 12.8 and TBR 75.3. Red arrow: size >5 mm. Inset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




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



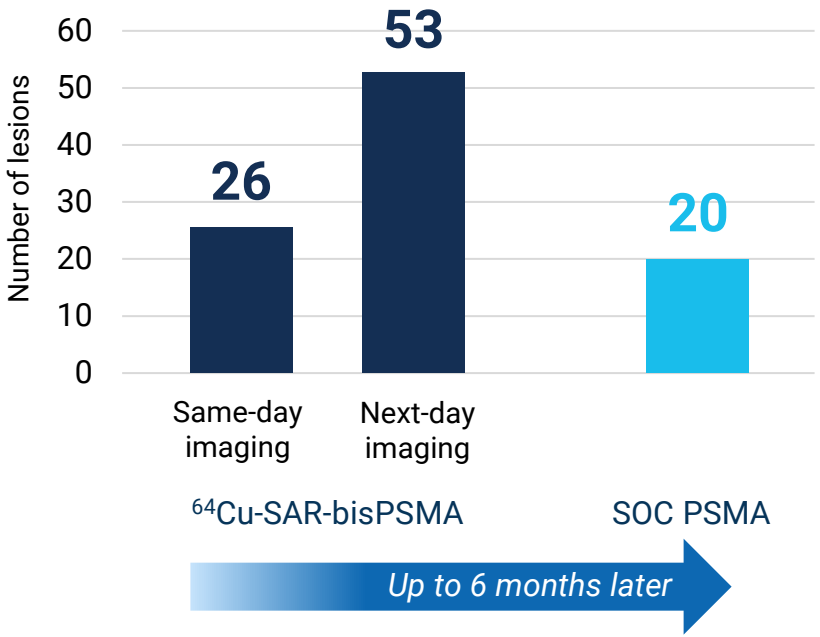

>5x higher mean TBR (same-day vs. next-day imaging)

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 $^{64}$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.

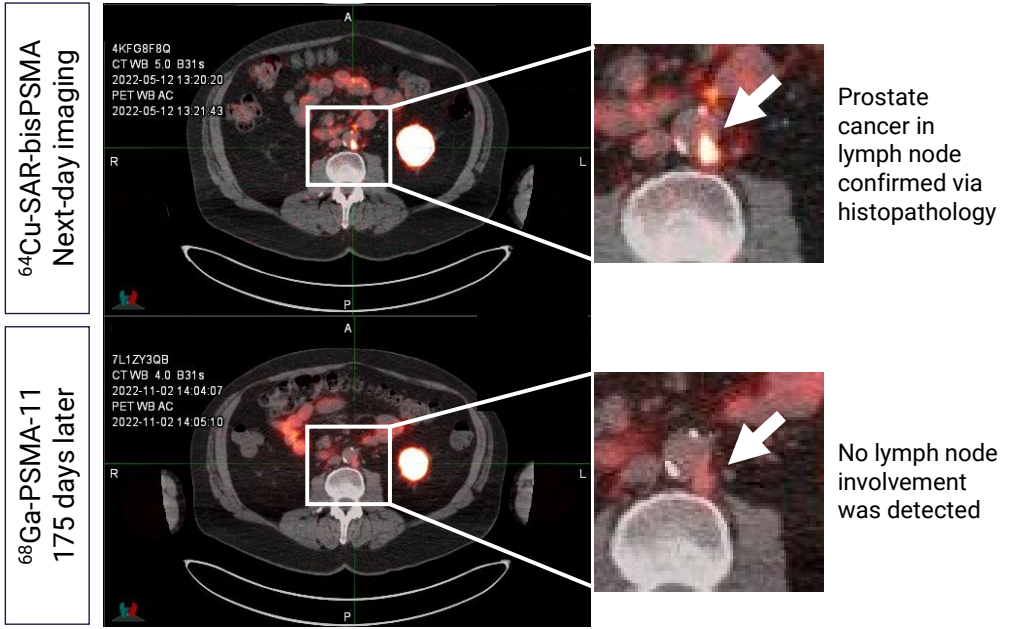
# $^{64}$Cu-SAR-bisPSMA identifies lesions months before currently approved PSMA PET agents

COBRA

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




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




Graph: Average number of lesions identified by the readers on same-day, next-day imaging ($^{64}$Cu-SAR-bisPSMA) or standard of care (SOC) PSMA PET ($^{68}$Ga-PSMA-11 or $^{18}$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 $^{64}$Cu-SAR-bisPSMA on next-day imaging (confirmed by all 3 readers). $^{68}$Ga-PSMA-11 scan performed 176 days post-Day 0 (175 days post-Day 1) did not show uptake of tracer. PET/CT fusion.

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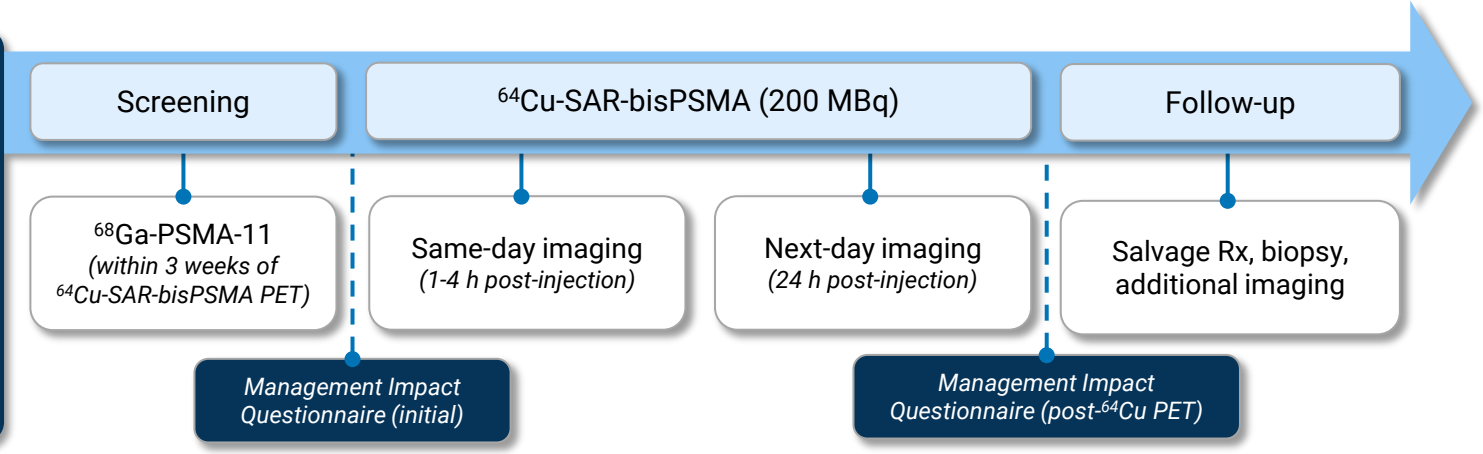
# Co-PSMA IIT achieves primary endpoint: Head-to-head trial of $^{64}$Cu-SAR-bisPSMA vs. $^{68}$Ga-PSMA-11 in low-PSA BCR

***Patient population***

- Prior radical prostatectomy (confirmed adenocarcinoma of PC)
- Rising PSA (0.20 – 0.75 ng/mL)
- No prior salvage radiotherapy




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

Full results of this study will be presented at an upcoming international conference. Investigator Initiated Trial (IIT) conducted by Prof Louise Emmett, St Vincent's Hospital (Sydney, Australia). PSA: prostate-specific antigen. PC: prostate cancer. Rx: radiotherapy. PET: positron emission tomography. CT: computed tomography. BCR: biochemical recurrence. NCT06907641.

# Thank you

## Contact details

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