CLARITY PHARMACEUTICALS

SAR-bisPSMA:
Made in Australia.
Built for success.

Bioshares Biotech Summit

Dr Alan Taylor
Executive Chairperson

6-7 Aug 2026

All Clarity products mentioned in this presentation are investigational products and not approved by the US Food and Drug Administration (FDA).

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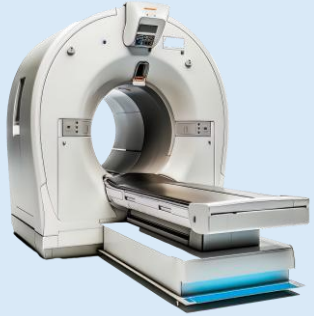
Clarity’s Vision: from Australia’s benchtop to blockbuster

Building Australia's most successful pharmaceutical biotech from intellectual property (IP) derived from the benchtop of Australian science

Discovery in Australia’s leading research organisations, generating strong IP



Clinical development to the highest standard of scientific rigour

Commercialisation into blockbuster markets with high unmet needs

Australian science that created pharmaceutical blockbusters

Blockbuster status, i.e. more than US$1 billion in annual sales, is a milestone only a few products originated from Australian science have ever reached

Gardasil

HPV (Human papillomavirus) vaccine for the prevention of cervical, anal and genital cancers

USD 8.9Bn in 2023

Origin: University of Queensland

Commercialisation: CSL & Merck (MSD)

Venclexta

Targeted cancer therapy for blood cancers like Chronic Lymphocytic Leukemia and Acute Myeloid Leukemia

USD 1.3Bn in 2025

Origin: Walter and Eliza Hall Institute

Commercialisation: AbbVie and Roche/Genentech

Relenza

Anti-viral medication to treat and prevent influenza

~USD 1.0Bn in 2009

Origin: Monash University, ANU CSIRO & Biota

Commercialisation: GlaxoSmithKline (GSK)

Ojjaara

Oral medication to treat myelofibrosis

USD 835M 2025

Origin: Ludwig Institute for Cancer Research Melbourne

Commercialisation: GlaxoSmithKline (GSK)

NEXT CHAPTER

^{64}Cu-SAR-bisPSMA

Targeted Copper Theranostics, PSMA PET diagnostics

Multi-billion

Market size prediction for 2030+

Aiming to join Australia's blockbuster club

Origin: Collaboration between University of Melbourne and Clarity

Development:

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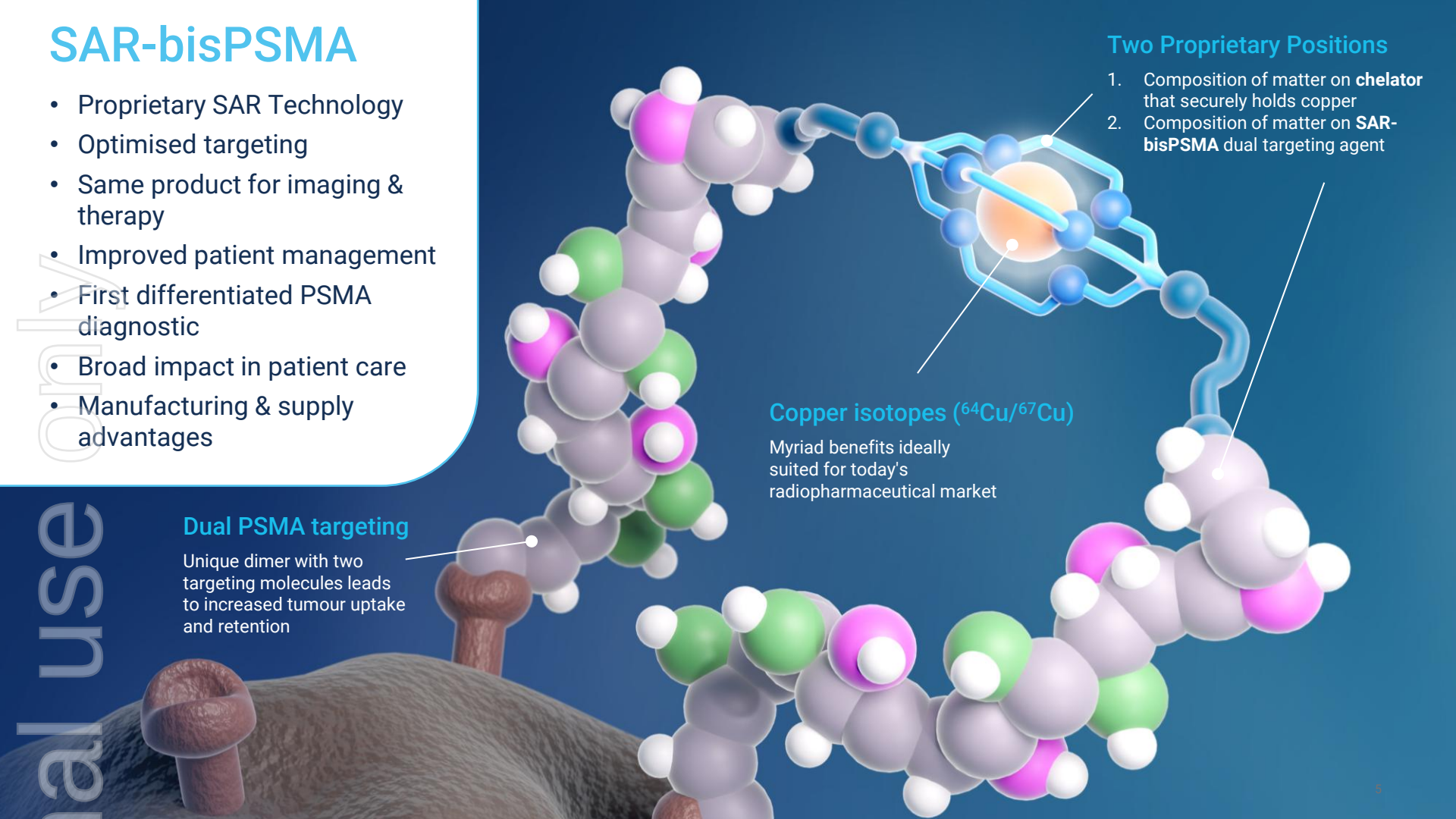
Sources: Company Financial Reports - Merck MSD for Gardasil (2023), Abbvie for Venclexta (2025) and GlaxoSmithKline for Relenza (2009). https://www.datainsightsmarket.com/reports/momelotinib-1148805 for Ojjaara. This may be a non-exhaustive list. Revenues shown for context only; not a forecast of Clarity's results. "Multi-billion" refers to the total future potential prostate-specific membrane antigen (PSMA) positron emission tomography (PET) diagnostic market.

SAR-bisPSMA

- Proprietary SAR Technology
- Optimised targeting
- Same product for imaging & therapy
- Improved patient management
- First differentiated PSMA diagnostic
- Broad impact in patient care
- Manufacturing & supply advantages



Two Proprietary Positions

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

Copper isotopes (^{64}Cu/^{67}Cu)

Myriad benefits ideally suited for today's radiopharmaceutical market

Dual PSMA targeting

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

Three FDA Fast Track Designations granted

Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. Fast Track addresses a broad range of serious conditions.

Diagnostic: ^{64}Cu-SAR-bisPSMA

PET imaging of PSMA-positive prostate cancer lesions in:

1. Patients with suspected metastasis who are candidates for initial definitive therapy;
2. Patients with biochemical recurrence of prostate cancer following definitive therapy

Therapy: ^{67}Cu-SAR-bisPSMA

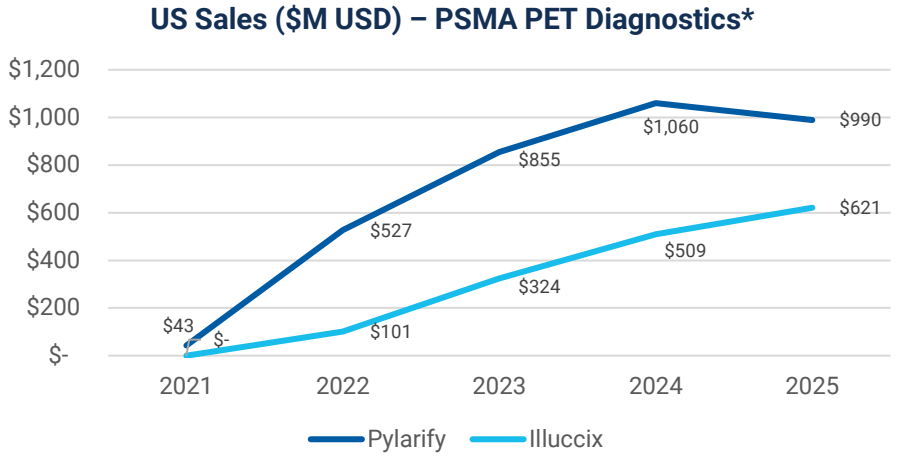
3. Treatment of adult patients with PSMA-positive metastatic castration-resistant prostate cancer (mCRPC) who have been previously treated with an androgen receptor pathway inhibitor (ARPI).

SAR-bisPSMA diagnostic market opportunity

SAR-bisPSMA aims to disrupt current diagnostic and therapeutic utilisation as a potential best-in-class agent for imaging and treating prostate cancer

PSMA-based diagnostics: Significant market opportunity

- By 2030 the PSMA PET market is expected to grow to **>700k** scans per year, representing a US market potential of **>US$3Bn/year**
- As PSMA PET use expands to **additional patient populations in 2030+,** the market is expected to continue to **grow to US$5-6Bn**
- 2025 US Centres for Medicaid and Medicare Services (CMS) reimbursement changes favour the long-term potential of the best-in-class PSMA PET agent



*US sales for Locametz, Posluma and other PSMA PET diagnostics are not publicly available. Data pulled from Telix and Lantheus press releases and investor reports.

Australian innovation challenging the PSMA PET standard

	^{64}Cu-SAR-bisPSMA	^{68}Ga-PSMA-11[1,2]*	^{18}F-DCFPyL[3,4]*	^{18}F-rhPSMA-7.3[5,6]*
Country of origin of the innovation	Australia	Germany	US	Germany
Innovator	University of Melbourne / Clarity collaboration	German Cancer Research Center (DKFZ), Heidelberg	Johns Hopkins University	Technical University of Munich (TUM)
Clinical development sponsor	Clarity	Academia	Progenics/Lantheus	Blue Earth Diagnostics
Patent	Active	No patent protection	Active	Active
Targeting moiety	Dimer targeting PSMA	Monomer targeting PSMA	Monomer targeting PSMA	Monomer targeting PSMA
Isotope half-life	^{64}Cu (12.7 h)	^{68}Ga (1.1 h)	^{18}F (1.8 h)	^{18}F (1.8 h)
Product shelf-life	Up to 48 h	6 h	10 h	10 h
Imaging window (post-administration)	1 to 30 hrs	50 to 100 min ⊘	1 h ⊘	1 h
Sensitivity	CLARIFY	40% (prespecified endpoint not met)	40% (prespecified endpoint not met)	27% (prespecified endpoint not met)
Specificity	CLARIFY	95% (prespecified endpoint not met)	98%	95%

⊘ Delayed imaging with ^{68}Ga-PSMA-11 beyond 100 minutes not approved by FDA[2]

⊘ Starting image acquisition more than 90 minutes after injection may adversely impact imaging performance[4]

1. Hope T et al., JAMA Oncol. 2021;7;(11):1635-1642. 2.GOZELLIX® (gallium Ga 68 gozetotide injection) prescribing information. FDA; 2025. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219592s000lbl.pdf. 3. Pienta KJ et al Osprey J Urol. 2021;206(1):52-61. 4. PYLARIFY TRUVU® (piflufolastat F 18) prescribing information. FDA; 2026. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/220089Orig1s000lbl.pdf. 5. Surasi DS el al LIGHTHOUSE Eur Urol 2023;84:361-370. 6. POSLUMA® (flotufolastat F 18) prescribing information. FDA; 2023. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216023s000lbl.pdf. * Primary endpoints related to the registrational trials in the pre-prostatectomy setting respective to each product. Source: FDA Center for Drug Evaluation and Research, Multi-Discipline Review Differences in study design and patient populations preclude direct cross-trial comparisons. 64Cu-SAR-bisPSMA data on file.

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Sensitivity remains a major limitation of currently approved PSMA PET agents

None of the pivotal studies used for the registration of the currently FDA-approved PSMA PET agents met their predefined sensitivity primary endpoint

	Primary Endpoints*	
	Sensitivity#	Specificity#
^{68}Ga-PSMA-11[1]	40% ✗	95% ✗
^{18}F-rhPSMA-7.3[2]	27% ✗	95% ✓
^{18}F-DCFPyL[3]	40% ✗	98% ✓

- The **^{68}Ga-PSMA-11** pivotal study did not meet either its sensitivity or specificity primary endpoint
- The **^{18}F-rhPSMA-7.3** and **^{18}F-DCFPyL** registrational studies did not meet their sensitivity and consequently co-primary endpoints

The combination of low sensitivity and variability across clinical trials highlights the need for head-to-head studies to identify the PSMA PET agent of choice

*Primary endpoints related to the registrational trials in the pre-prostatectomy setting respective to each product. Source: FDA Center for Drug Evaluation and Research, Multi-Discipline Review.
#Sensitivity and specificity presented as reported in the published pivotal studies for each product. Differences in study design and patient populations preclude direct cross-trial comparisons.
1. Hope T et al. JAMA Oncol. 2021;7:1635-1642. 2. Surasi DS et al. Eur Urol. 2023;84:361-370. 3. Pienta et al. J Urol. 2021;206:52-61.

Monomer

^{177}Lu-PSMA-617*

^{18}F-DCFPyL*

^{18}F- rhPSMA-7.3*

^{68}Ga-PSMA-11*

^{64}Cu-PSMA-I&T

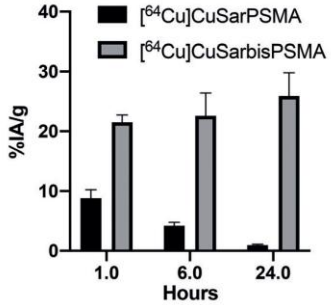
^{18}F-PSMA1007

* FDA-approved products

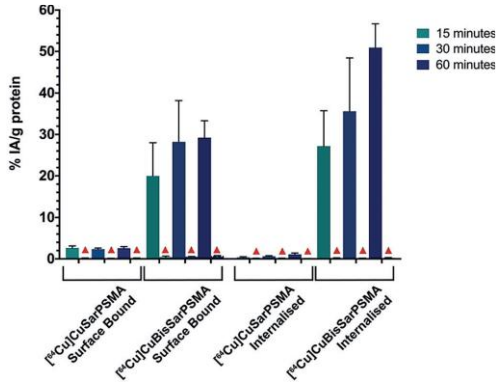
SAR-PSMA vs. SAR-bisPSMA

Monomer Dimer

Higher uptake and prolonged retention



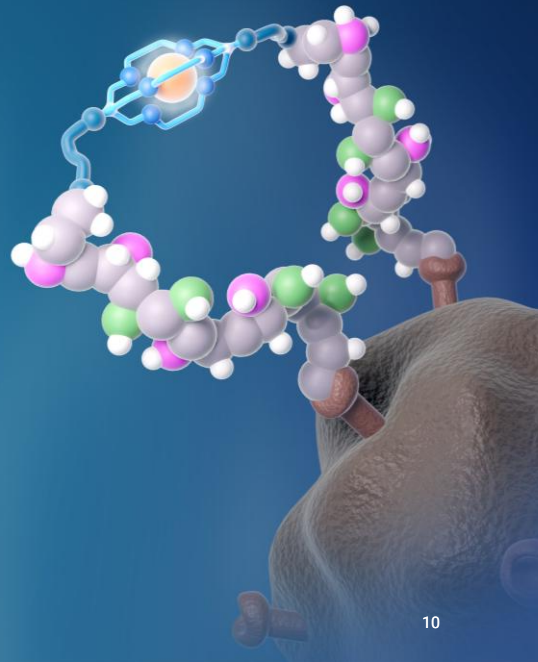
Considerably improved binding and internalisation



Zia et al., 2019. Ang.Chem

Dimer

$^{64/67}$Cu-SAR-bisPSMA



SAR-bisPSMA

Comprehensive clinical development program undertaken and body of evidence developed to date

Ongoing trials

CLARIFY - Phase III in pre-prostatectomy

- Registrational Phase III imaging trial of participants with high-risk prostate cancer prior to radical prostatectomy using ^{64}Cu-SAR-bisPSMA
- Recruitment ongoing

AMPLIFY – Phase III in BCR

- Registrational Phase III imaging trial with ^{64}Cu-SAR-bisPSMA in prostate cancer patients with biochemical recurrence (BCR)
- Recruitment completed, study ongoing

SECuRE - Phase I/IIa in mCRPC

- Theranostic trial for treatment of patients with mCRPC with ^{67}Cu-SAR-bisPSMA
- Dose Escalation (Phase I) successfully completed recruitment
- Cohort Expansion (Phase II) ongoing at 8 GBq dose level (enzalutamide combination allowed)

Completed trials

PROPELLER – Phase I in pre-prostatectomy

- First-in-human PET imaging trial of participants with confirmed prostate cancer using ^{64}Cu-SAR-bisPSMA in Australia
- Study completed, results released

COBRA – Phase I/II in BCR

- Phase I/II PET imaging trial of participants with BCR of prostate cancer following definitive therapy using ^{64}Cu-SAR-bisPSMA in the US
- Study completed, results released

Co-PSMA - Phase II Investigator-Initiated Trial in BCR

- Led by Prof Louise Emmett at St Vincent's Hospital Sydney
- Phase II head-to-head comparison of ^{64}Cu-SAR-bisPSMA vs. ^{68}Ga-PSMA-11 product for the detection of prostate cancer recurrence
- Study completed, results released

SAR-bisPSMA: a body of evidence built for success

Patients

750+

across trials and compassionate use access

Scans performed

1,500+

^{64}Cu-SAR-bisPSMA same-day and/or next-day imaging

Trials

6

Phase I to registrational Phase III and investigator-initiated trials

Countries

2

Australia and USA

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Data on file.

^{64}Cu-SAR-bisPSMA PET vs. SOC* PSMA PET

Performance of ^{64}Cu-SAR-bisPSMA PET vs. SOC PSMA PET assessed in all trials

PROPELLER[1]	CLARIFY[1]	COBRA[1]	Co-PSMA[2]	AMPLIFY[1]
SOC PSMA PET	SOC PSMA PET	SOC PSMA PET	SOC PSMA PET	SOC PSMA PET
Median 20.5 days (2-50) between both scans	Within 60 days of Day 1	Within 60 days of Day 0, up to 180 days follow-up	Median 2 days (IQR 1-8) between SOC and ^{64}Cu PET[3]	Within 60 days of Day 1, up to 180 days follow-up
^{64}Cu-SAR-bisPSMA PET	^{64}Cu-SAR-bisPSMA PET	^{64}Cu-SAR-bisPSMA PET	^{64}Cu-SAR-bisPSMA PET	^{64}Cu-SAR-bisPSMA PET
Exploratory endpoints • Number of lesions detected • Tracer uptake • Tumour-to-background ratio	**Exploratory endpoints** • Lesion detection	**Post-hoc analysis** • Lesion detection	**Primary endpoint** • Mean number of lesions detected per patient	**Exploratory endpoint** • Lesion detection

Intra-patient head-to-head comparison for confidence in decision making

* Standard-of-care (SOC) PSMA PET includes ^{68}Ga-PSMA-11 and ^{18}F-DCFPyL; IQR: interquartile range. 1. Data on file. 2. Khan et al. Eur Urol. 2026;89:512-520. doi: 10.1016/j.eururo.2026.03.001.
3. Interval between ^{68}Ga-PSMA-11 PET and ^{64}Cu-SAR-bisPSMA same-day PET.

^{64}Cu-SAR-bisPSMA in Pre-definitive Treatment Settings:

PROPELLER
CLARIFY

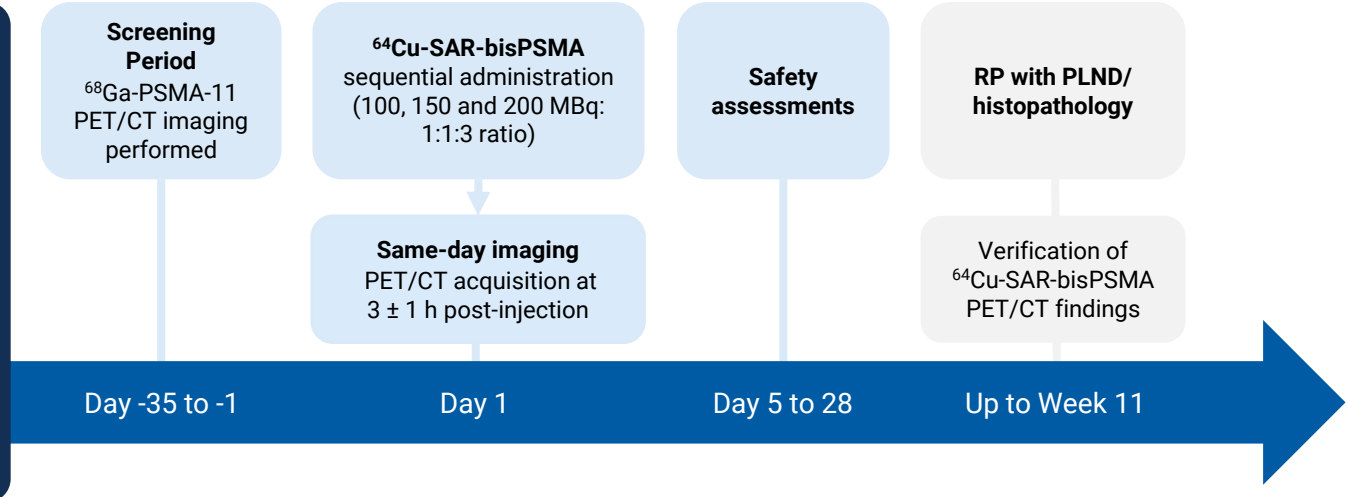
PROPELLER Phase I trial: completed

PROPELLER

First-in-human, dose-ranging study evaluating safety and preliminary efficacy of ^{64}Cu-SAR-bisPSMA in participants with untreated, histopathology-confirmed prostate cancer

Key eligibility criteria (n=30)

- Participants with untreated, histologically confirmed adenocarcinoma of the prostate electing to undergo RP with PLND
- Intermediate- to high-risk PC characterised by:
  - Clinical Stage ≥ T2b or ISUP Grade Group ≥ 3 or prostate-specific antigen (PSA) ≥ 10 ng/mL



- **Primary endpoints:** ***safety*** – incidence and severity of adverse events (AEs) and serious AEs following administration of ^{64}Cu-SAR-bisPSMA; ***efficacy*** – proportion of ^{64}Cu-SAR-bisPSMA PET/CT scans assessed as True Positive or False Negative for primary prostate cancer as confirmed by histopathology
- **Exploratory endpoints** include intra-patient head-to-head comparisons of the diagnostic performance of ^{64}Cu-SAR-bisPSMA vs. ^{68}Ga-PSMA-11

Additional eligibility criteria apply. ISUP: International Society of Urological Pathology; PC: prostate cancer; PLND: pelvic lymph node dissection; RP: radical prostatectomy. Investigational products only. Not approved by the FDA. For scientific exchange and non-promotional purposes only. ClinicalTrials.gov identifier: NCT04839367.

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^{64}Cu-SAR-bisPSMA yielded higher tumour uptake and detected more lesions than ^{68}Ga-PSMA-11 on same-day imaging in first head-to-head trial

PROPELLER

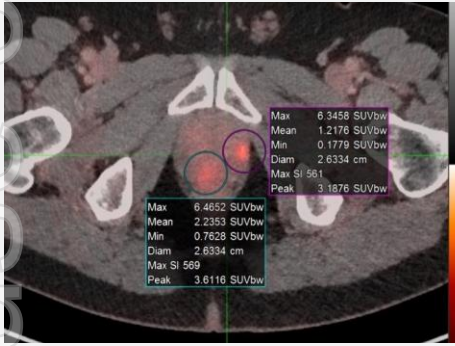
Improved diagnostic performance of ^{64}Cu-SAR-bisPSMA compared to ^{68}Ga-PSMA-11 on same-day imaging

Higher number of lesions identified

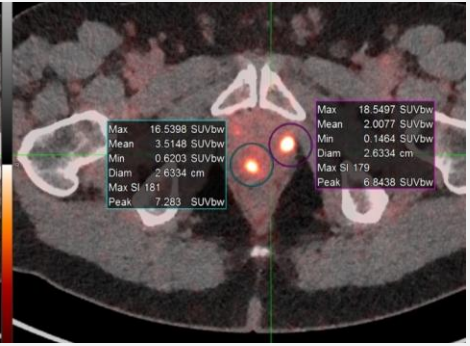
2-3 times higher uptake and tumour-to-background ratio

2-3x more uptake and contrast

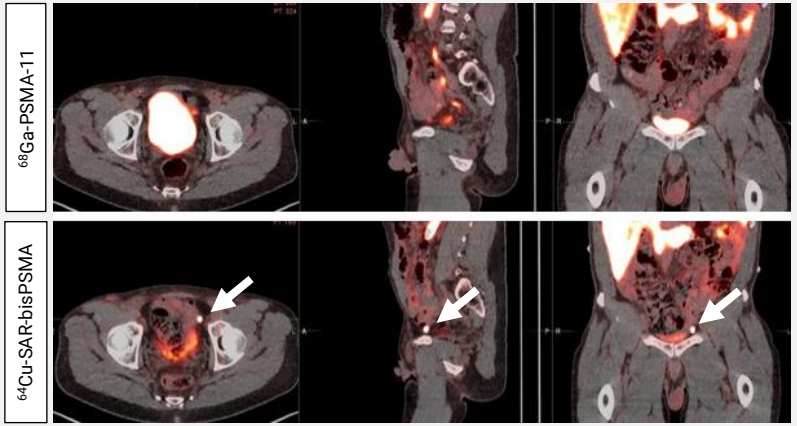
^{68}Ga-PSMA-11



^{64}Cu-SAR-bisPSMA



More lesions identified



Left images: concordant lesions (same patient). Maximum standardised uptake value (SUVmax), mean standardised uptake value (SUVmean), tumour-to-background ratio (TBR): 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 (prostate cancer confirmed by histopathology). Lengyelova & Emmett et al. PROPELLER study. ASCO, 2023. ClinicalTrials.gov identifier: NCT04839367.

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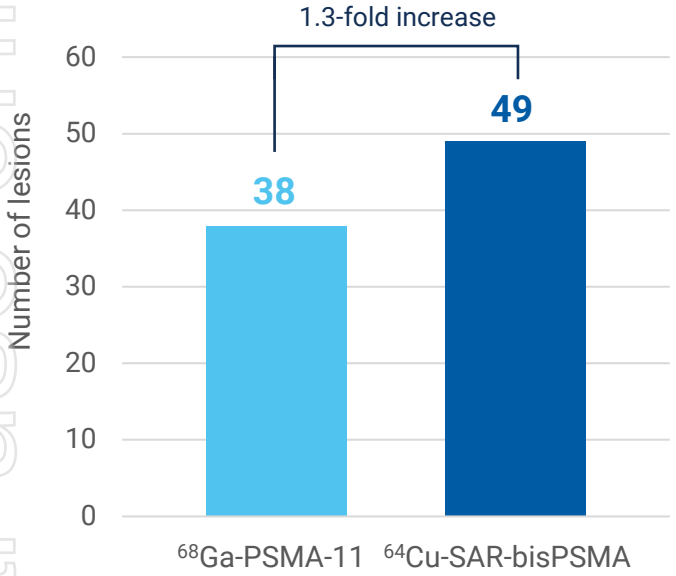
^{64}Cu-SAR-bisPSMA identifies more lesions on same-day imaging vs. ^{68}Ga-PSMA-11

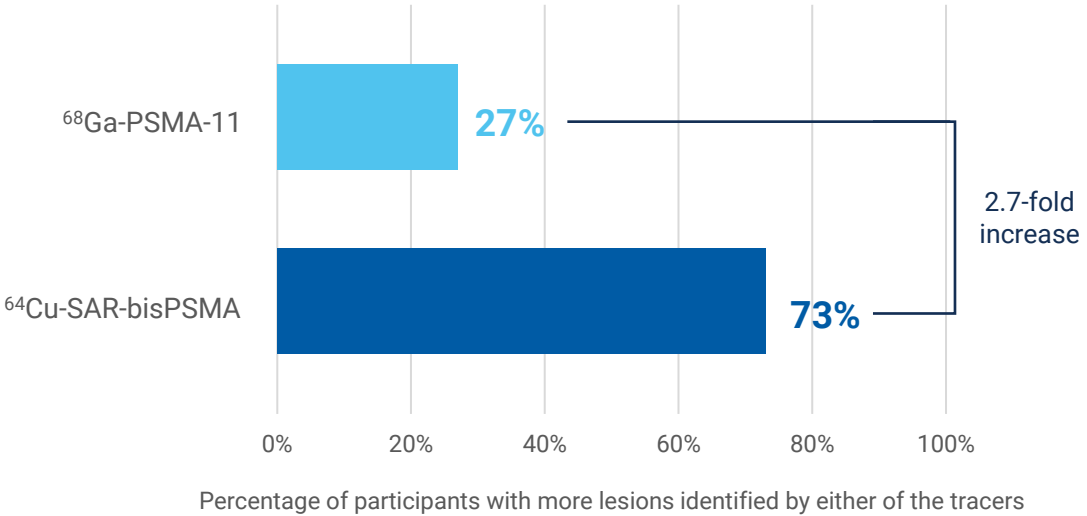
PROPELLER

Prospective intra-patient comparison demonstrates that ^{64}Cu-SAR-bisPSMA same-day imaging detects more lesions than ^{68}Ga-PSMA-11 and outperforms it in most participants

^{64}Cu-SAR-bisPSMA identified more total number of lesions than ^{68}Ga-PSMA-11*



Among participants with discordant lesion findings, ^{64}Cu-SAR-bisPSMA detected more lesions in more participants than ^{68}Ga-PSMA-11†



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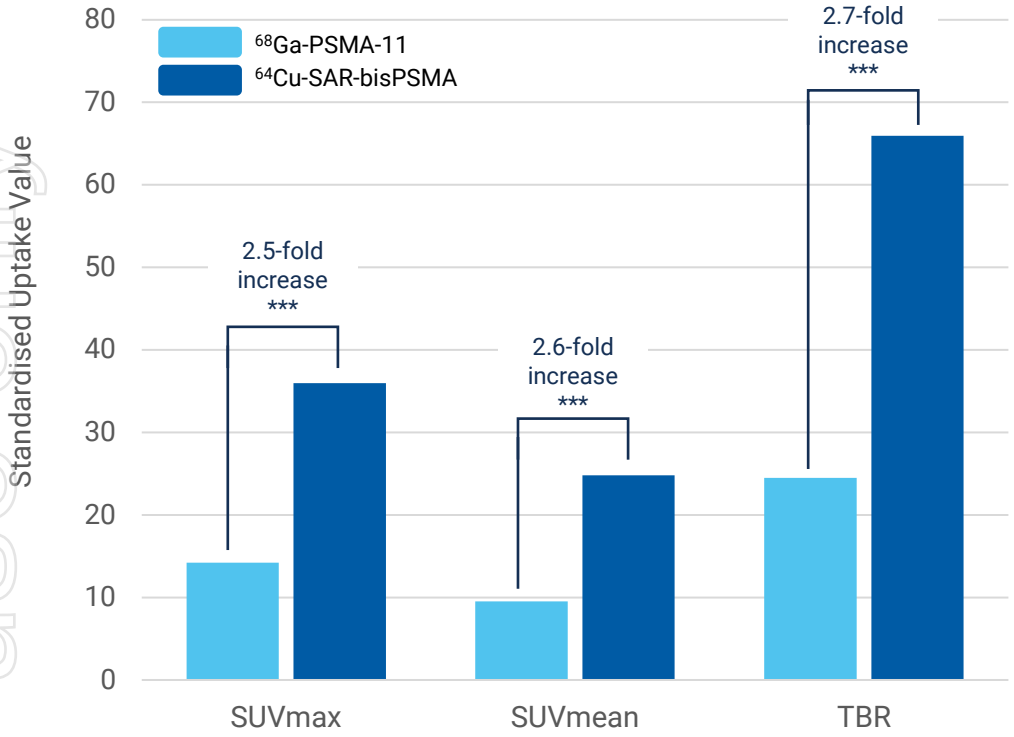
*Averaged across all readers, all participants; †Averaged across all readers, participants with discordant lesions only are presented. ClinicalTrials.gov identifier: NCT04839367.

^{64}Cu-SAR-bisPSMA shows higher lesion uptake and TBR vs. ^{68}Ga-PSMA-11 on same-day imaging

PROPELLER



^{64}Cu-SAR-bisPSMA scans were associated with statistically significant:

- Higher SUVmax
- Higher SUVmean
- Higher tumour-to-background ratio

*** Denotes p<0.0001 as assessed by two-sided Wilcoxon signed-rank test on the comparison of the two imaging methods. Values were derived from the average of medians from each reader. The lesions were averaged for each patient so that each patient contributes once to the summary statistics. Lengyelova et al. PROPELLER study. ASCO, 2023; ClinicalTrials.gov identifier: NCT04839367. Data on file.

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PROPELLER: First-in-human study

PROPELLER

First study to demonstrate improved diagnostic performance of ^{64}Cu-SAR-bisPSMA PET over SOC PSMA PET in detecting primary prostate cancer prior to prostatectomy

^{64}Cu-SAR-bisPSMA PET outperformed ^{68}Ga-PSMA-11 PET in this head-to-head comparison in pre-prostatectomy patients based on:

- **Higher lesion detection:** Greater total number of lesions and higher percentage of participants with more lesions
- **Better image quality:** Higher tracer uptake and improved background contrast
- **Favourable tolerability:** Well tolerated in all 30 participants with only a single related AE of Grade 1 dysgeusia (metallic taste) reported

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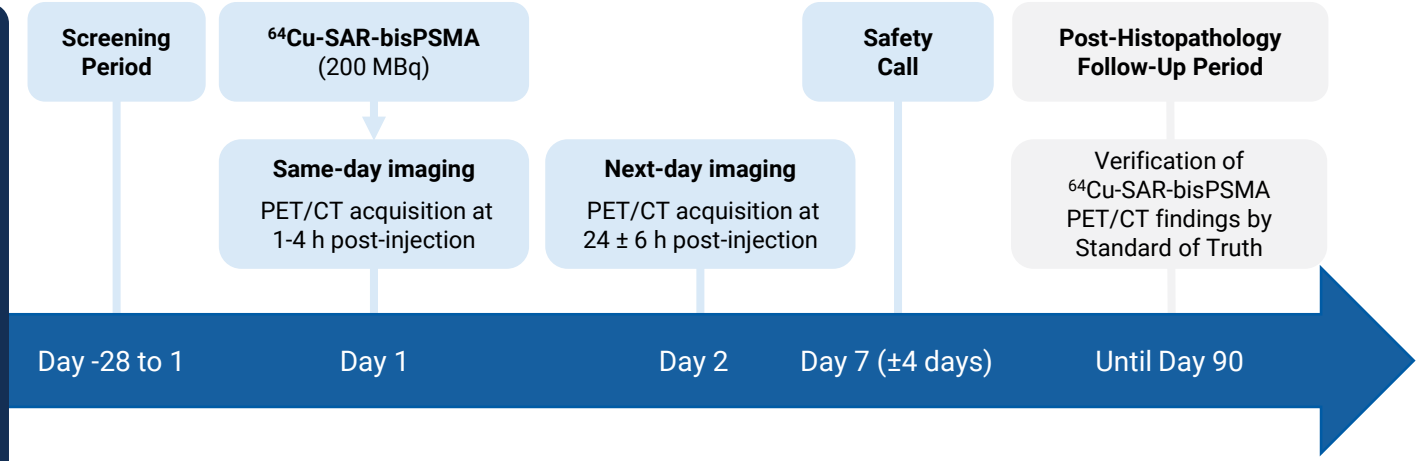
ClinicalTrials.gov identifier: NCT04839367. Data on file.

CLARIFY Phase III trial: recruiting

Registrational trial in participants with high-risk prostate cancer prior to undergoing radical prostatectomy and pelvic lymph node dissection

Key eligibility criteria (n=383)

- Untreated, histopathology-confirmed adenocarcinoma of the prostate
- High-risk or greater PC defined by NCCN Guidelines as:
  - Clinical Stage ≥ T3a or
  - Grade Group ≥ 4 or
  - PSA > 20 ng/mL
- Proceeding to RP with pelvic lymph node dissection PLND



- **Primary endpoint:** Co-primary endpoints of sensitivity and specificity of ^{64}Cu-SAR-bisPSMA PET compared to Standard of Truth, assessed independently for same-day and next-day imaging
- **Exploratory endpoints** include intra-patient head-to-head comparisons of the diagnostic performance of ^{64}Cu-SAR-bisPSMA vs. SOC PSMA PET agents

Additional eligibility criteria apply. NCCN: National Comprehensive Cancer Network. Investigational products only. Not approved by the FDA. For scientific exchange and non-promotional purposes only. ClinicalTrials.gov identifier: NCT06056830.

^{64}Cu-SAR-bisPSMA in biochemical recurrence:

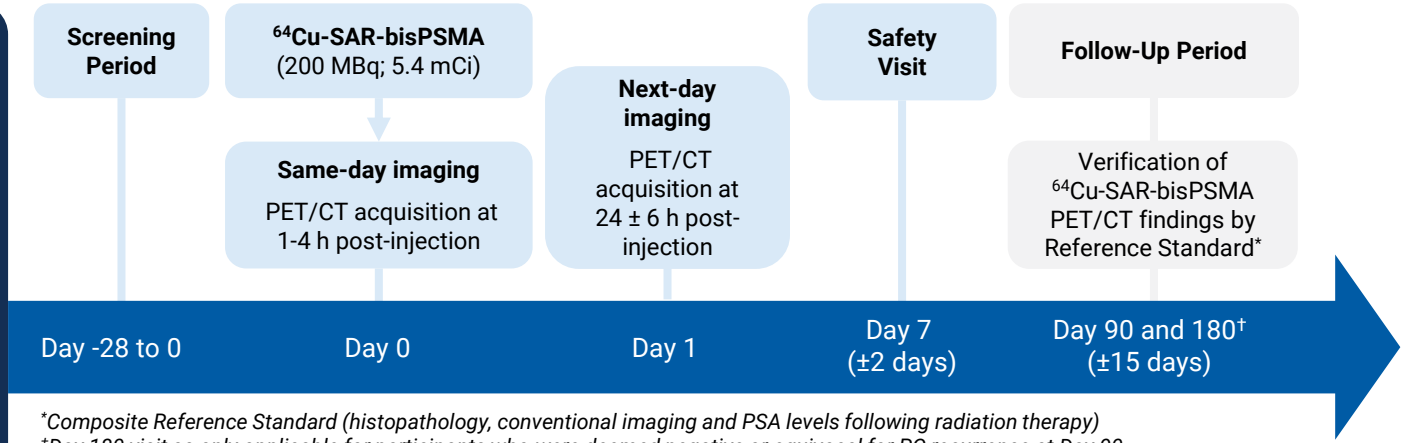
COBRA
AMPLIFY
Co-PSMA

COBRA Phase I/II trial: completed

Phase I/II trial assessing the safety and efficacy of ^{64}Cu-SAR-bisPSMA in patients with BCR of prostate cancer and negative or equivocal SOC imaging

Key eligibility criteria (n=50)

- Confirmed adenocarcinoma of the prostate with subsequent definitive therapy
- Suspected recurrence of PC based on rising or detectable PSA
- Negative or equivocal findings for PC on conventional imaging per SOC within 60 days prior to Day 0



Composite Reference Standard (histopathology, conventional imaging and PSA levels following radiation therapy)
†Day 180 visit as only applicable for participants who were deemed negative or equivocal for PC recurrence at Day 90

Key primary endpoints

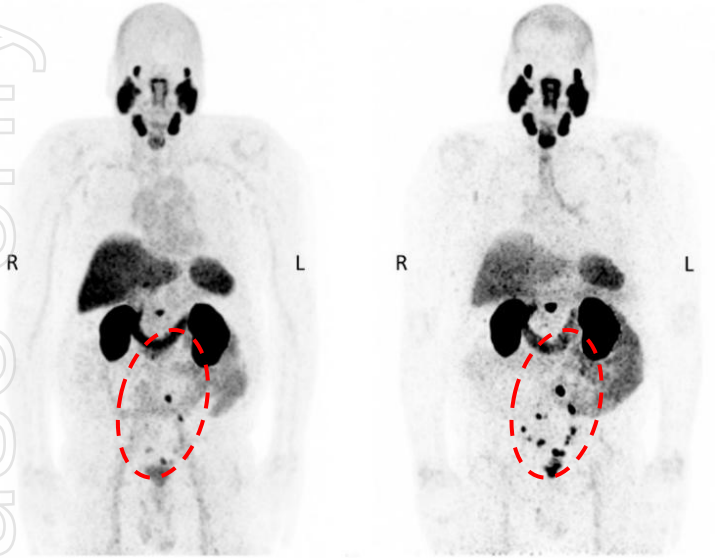
- Incidence and severity of treatment-emergent AEs and Serious AEs following the administration of ^{64}Cu-SAR-bisPSMA
- Assessed independently for same-day and next-day imaging: Correct detection rate (CDR) defined as the proportion of true-positive participants out of all scanned participants who had at least one evaluable reference standard datapoint

More lesions and patients with a positive scan identified by ^{64}Cu-SAR-bisPSMA on next-day imaging

COBRA

^{64}Cu-SAR-bisPSMA

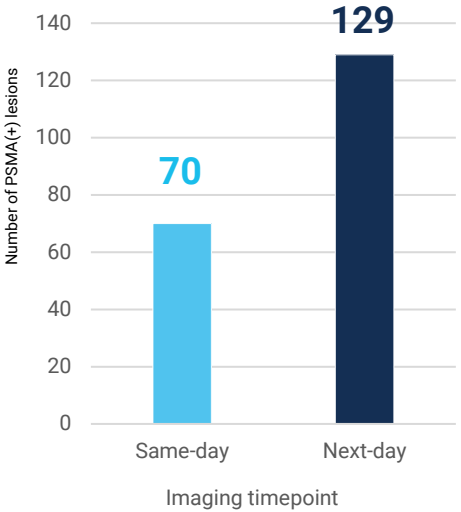
Same-day imaging	Nex-day imaging



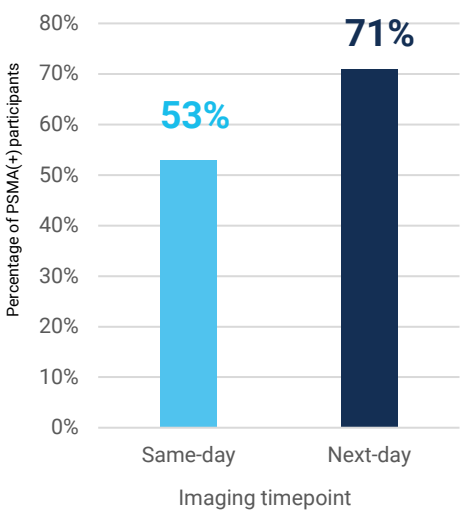
^{64}Cu-SAR-bisPSMA PET showing positive lymph nodes in the pelvic, extra-pelvic (retroperitoneal) and lesions in the prostatic bed regions

Next-day imaging identified additional lesions compared to same-day imaging

The number of lesions identified by ^{64}Cu-SAR-bisPSMA **increased by 82%***



% of ^{64}Cu-SAR-bisPSMA PET-positive participants **increased by 34%**†



*Average increase across readers of 82% (from same to next-day imaging). Ranges across the readers for the total number of lesions detected: 53–80 on same-day vs. 82–153 on next-day imaging. Full Analysis Set: 42 patients. †Average increase across readers of 34% (from same to next-day imaging). Detection rate (DR) range across the readers on same-day imaging was 44–58% (95% confidence interval [CI] 30–71.8), increasing on next-day imaging to 58–80% (95% CI 43.2–90). AEs: One related AE reported across the trial population (grade 2 worsening of type II diabetes, resolved). Images are displayed at maximum intensity projection. Nordquist et al. COBRA. EANM, 2024. ClinicalTrials.gov identifier: NCT05249127. Data on file.

CLARITY PHARMACEUTICALS

Higher uptake and contrast in lesions on next-day vs. same-day imaging allows for detection of lesions in the 2-millimeter range

COBRA

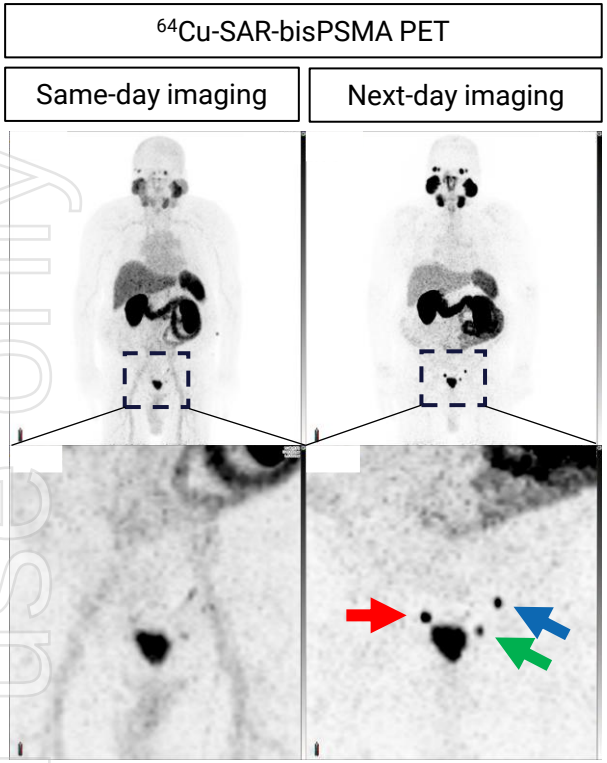
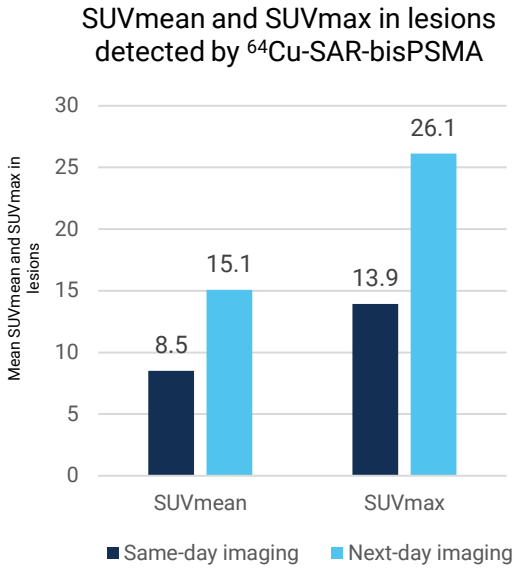
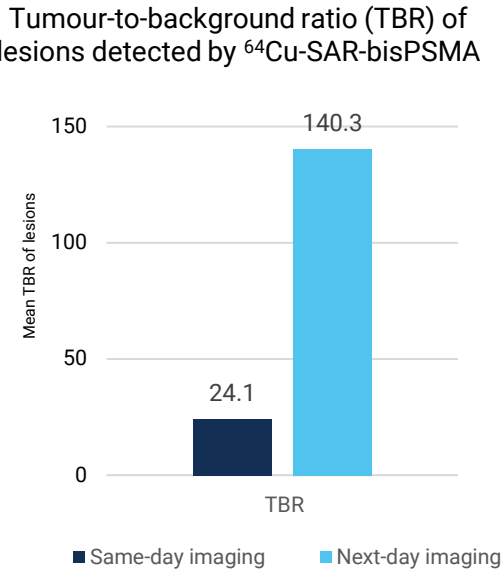


Figure 1. Pelvic lymph nodes showing uptake of ^{64}Cu-SAR-bisPSMA on next-day imaging. Blue arrow: lymph node size 3.8 mm x 4.4 mm, SUVmean 20.6, SUVmax 22.1 and TBR 130.1. Green arrow: lymph node size also 3.8 mm x 4.4 mm, SUVmean 11.9, SUVmax 12.8 and TBR 75.3. Red arrow: lymph node showing ^{64}Cu-SAR-bisPSMA uptake (>5 mm). Maximum Intensity Projection.





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

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

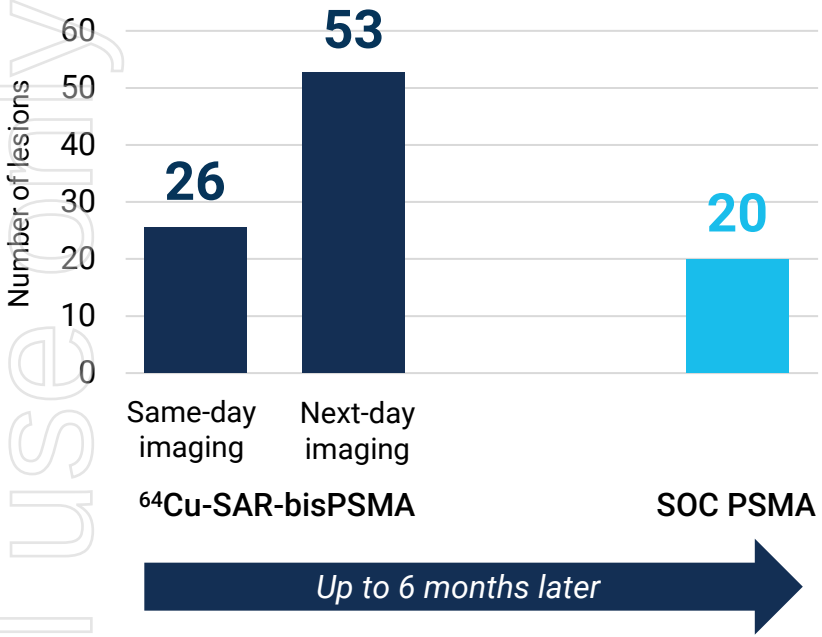
Figure 2. SUVmean/max and TBR comparing same-day and next-day imaging. Average increase across 3 readers. The SUVmax, SUVmean and TBR were assessed in up to 25 lesions per patient on each ^{64}Cu-SAR-bisPSMA scan. Ranges across the readers for same-day and next-day imaging, respectively: SUVmean 6.6-9.9 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.

ClinicalTrials.gov identifier: NCT05249127. Data on file.

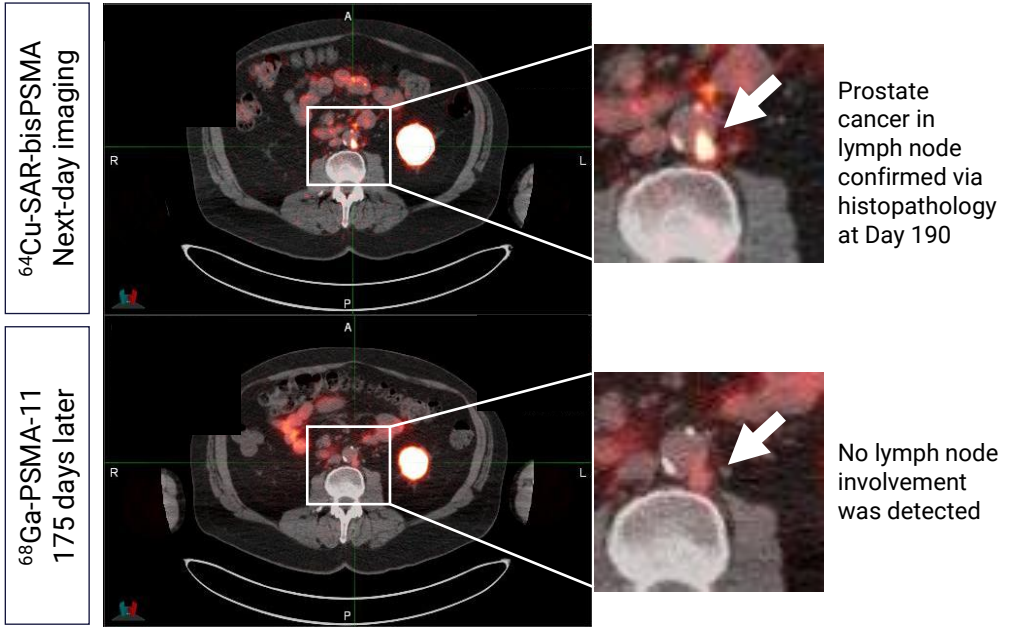
^{64}Cu-SAR-bisPSMA identifies lesions months before currently approved PSMA PET agents

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 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. Nordquist et al. COBRA. EANM, 2024. ClinicalTrials.gov identifier: NCT05249127. Data on file.

CLARITY PHARMACEUTICALS

^{64}Cu-SAR-bisPSMA: closing the diagnostic gap in prostate cancer recurrence

BCR patients with a negative/equivocal SOC scan at study entry

- **Next-day imaging increased lesion detection by 82%**, with the total number of identified lesions increasing from 70 to 129 (average across readers)
- **More participants were identified as PSMA-positive on next-day imaging, increasing from 53% to 71%**, representing a 34% increase versus same-day imaging (average across readers)
- **Over 80% higher tracer uptake in lesions and >5x higher contrast on next-day imaging enabled the detection of small lesions**, including lesions in the 2 mm range
- In a subset of participants, **^{64}Cu-SAR-bisPSMA identified 53 lesions on next-day imaging versus 20 lesions detected by SOC PSMA PET performed up to 6 months later**, demonstrating the ability to detect recurrent disease earlier

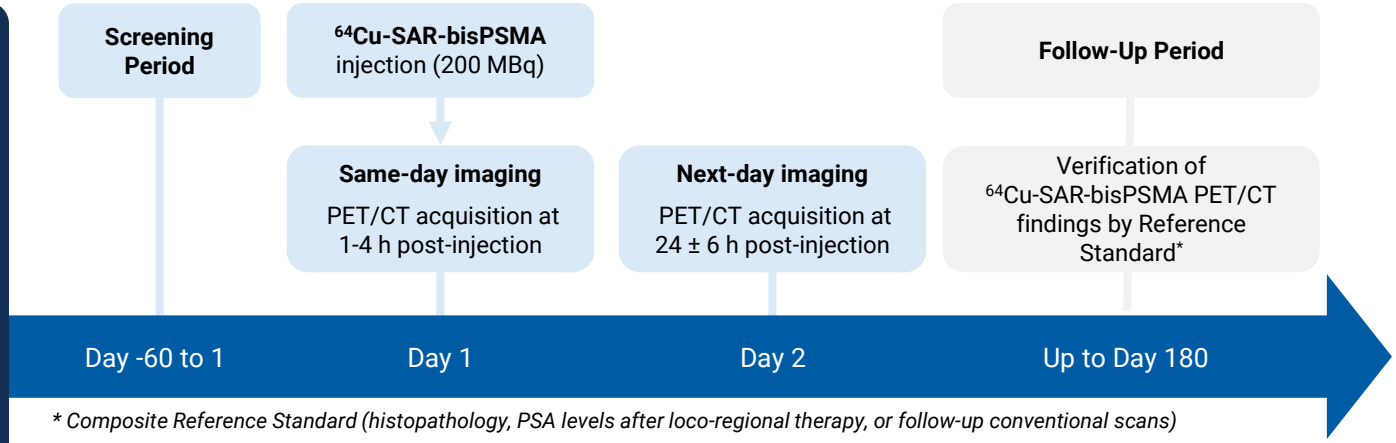
ClinicalTrials.gov identifier: NCT05249127. Data on file.

AMPLIFY Phase III trial: recruitment completed with 232 patients dosed and imaged

Registrational trial of participants with BCR of prostate cancer at sites in the US and Australia

Key eligibility criteria (n=220)

- Histologically confirmed adenocarcinoma of prostate per original diagnosis and completed subsequent definitive therapy.
- Rising or detectable PSA level after definitive therapy.
  - Post-radical prostatectomy: detectable or rising PSA that is ≥ 0.2 ng/mL with confirmatory PSA that is ≥ 0.2 ng/mL or
  - Post-radiation therapy, cryotherapy, or brachytherapy: increase in PSA level that is elevated by ≥ 2 ng/mL above the nadir.



** Composite Reference Standard (histopathology, PSA levels after loco-regional therapy, or follow-up conventional scans)*

- **Primary endpoint:** Co-primary endpoints of participant-level correct detection rate (CDR) and region-level positive predictive value (PPV), assessed independently for same-day and next-day imaging†
- **Exploratory endpoints** include intra-patient head-to-head comparisons of the diagnostic performance of ^{64}Cu-SAR-bisPSMA vs. SOC PSMA PET agents

Additional eligibility criteria apply. Investigational products only. Not approved by the FDA. For scientific exchange and non-promotional purposes only. ClinicalTrials.gov identifier: NCT06970847.

Co-PSMA Phase II investigator-initiated trial: completed

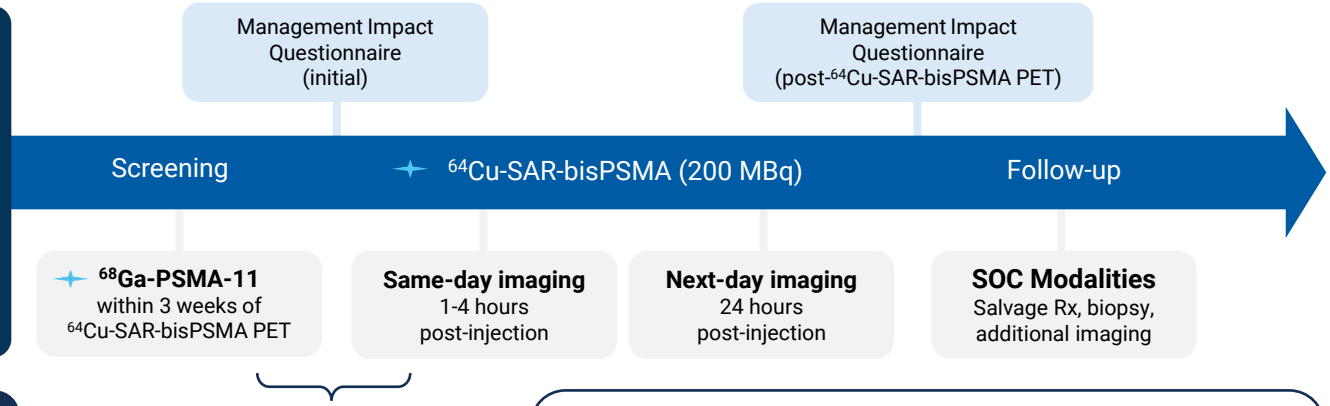
This prospective single-arm imaging trial enrolled 50 participants and evaluated the comparative performance of ^{64}Cu-SAR-bisPSMA vs. ^{68}Ga-PSMA-11

Key Eligibility

- Prior radical prostatectomy (confirmed adenocarcinoma of PC)
- Rising PSA 0.2 – 0.75ng/mL
- No prior salvage radiotherapy
- Under consideration for salvage fossa radiotherapy

Key Exclusion

- Prior salvage radiotherapy
- ADT currently or within prior 12 months
- Prior systemic therapy for PC



Primary objective:

- To compare the detection rate of PC lesions per participant, between ^{64}Cu-SAR-bisPSMA and ^{68}Ga-PSMA-11 PET/CT

Key secondary objectives:

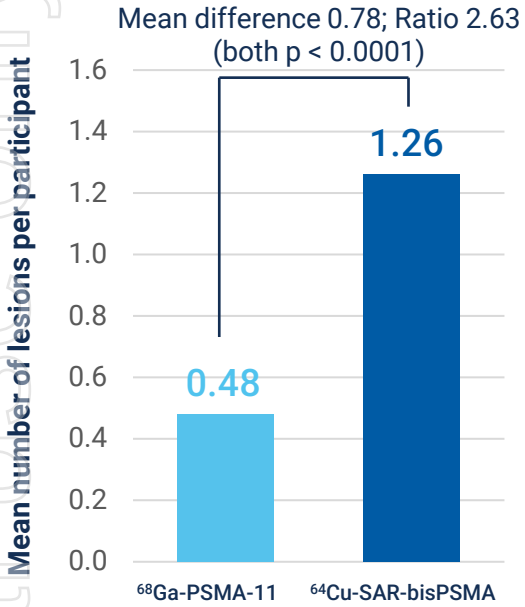
- To compare the diagnostic accuracy of ^{64}Cu-SAR-bisPSMA vs. ^{68}Ga-PSMA-11 PET/CT using a composite standard of truth
- To evaluate the magnitude of clinical management change when using ^{64}Cu-SAR-bisPSMA additional to standard of care imaging (^{68}Ga-PSMA-11)
- To evaluate PSA response following salvage Rx by ^{64}Cu-SAR-bisPSMA and ^{68}Ga PSMA-11 PET/CT imaging parameters

Investigator Initiated Trial (IIT conducted by Prof Louise Emmett, St Vincent's Hospital (Sydney, Australia). Rx: radiotherapy. NCT06907641, Khan et al. Eur Urol. 2026;89:512-520. doi: 10.1016/j.eururo.2026.03.001.

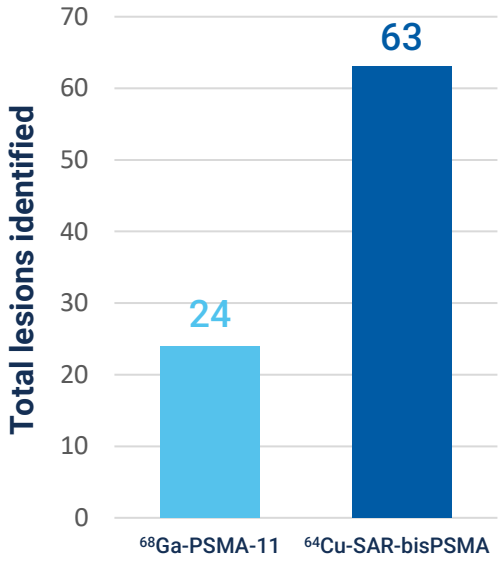
Co-PSMA: Improved diagnostic performance with next-day ^{64}Cu-SAR-bisPSMA PET vs. ^{68}Ga-PSMA-11 in early BCR*

^{64}Cu-SAR-bisPSMA detected **2.6x more lesions per patient** than ^{68}Ga-PSMA-11

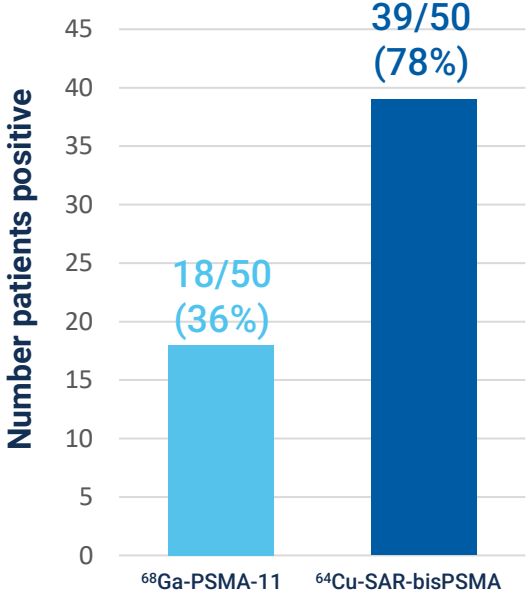
Number of lesions per participant



Total number of lesions



Participants with a positive scan



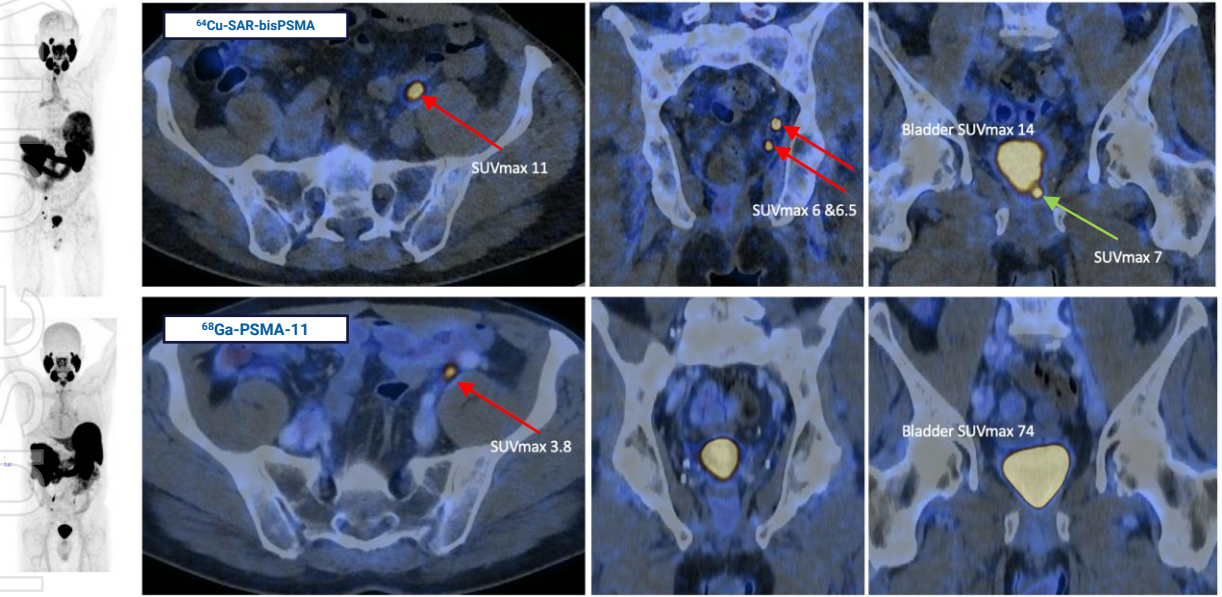
* Patients with confirmed BCR following radical prostatectomy with a PSA 0.2-0.75 ng/mL; Khan S, et al. Co-PSMA trial. Eur Urol. 2026; https://doi.org/10.1016/j.eururo.2026.03.001

Khan et al. Eur Urol. 2026;89:512-520. doi: 10.1016/j.eururo.2026.03.001

Co-PSMA: ^{64}Cu-SAR-bisPSMA detected more lesions per patient and a higher true positive rate than ^{68}Ga-PSMA

Near-perfect inter-reader agreement: very high level of reliability in scan interpretation between different nuclear medicine specialists
Kappa score of 0.94 (95% CI: 0.83-1.00) for vs. 0.75 (95% CI: 0.56-0.94) for ^{68}Ga-PSMA-11

Next-day ^{64}Cu-SAR-bisPSMA PET scan identified 4 lesions vs. 1 lesion with ^{68}Ga-PSMA-11

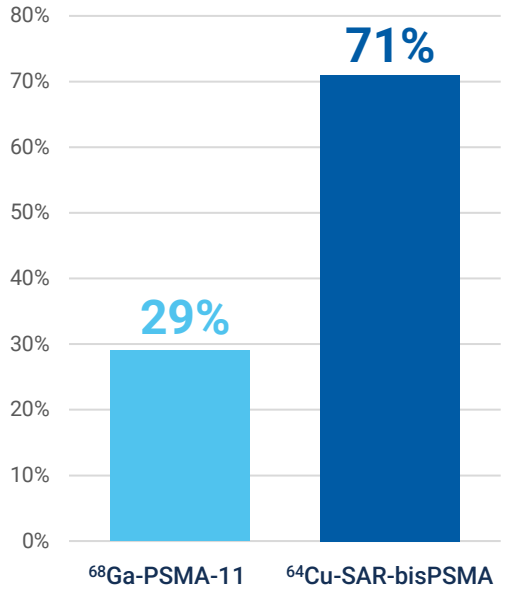


Adapted from *Khan* et al., European Urology 2026

Nodal lesion

Local recurrent lesion

True positive rate*



* True positive rate was derived from a composite reference standard as defined in Khan et al., European Urology. 2026;89:512-520. doi: 10.1016/j.eururo.2026.03.001

Co-PSMA: Next-day ^{64}Cu-SAR-bisPSMA PET drove treatment change in more participants with early BCR* in comparison to ^{68}Ga-PSMA-11

^{68}Ga-PSMA-11

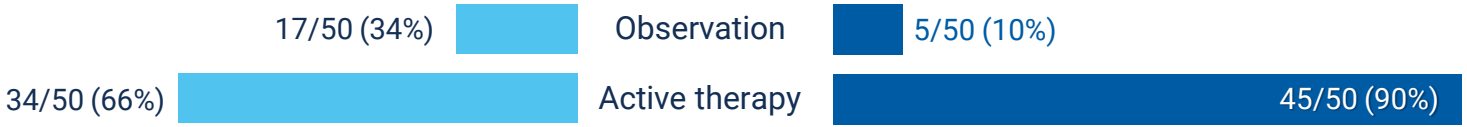
66%

of participants with planned active management

^{64}Cu-SAR-bisPSMA

90%

of participants with planned active management



44% of patients (22/50) underwent a treatment change based on the ^{64}Cu-SAR-bisPSMA scans

55% (12/22) changed from observation to targeted radiation therapy
40% (9/22) changed radiation fields
14% (3/22) added SBRT
18% (4/22) added ADT

*Patients with confirmed BCR following radical prostatectomy with a PSA 0.2-0.75 ng/mL.
LN: lymph node; fossa RTX :surgical fossa radiotherapy; SBRT: stereotactic body radiation therapy.
Khan et al., Eur Urol 2026;89:512–520; doi: 10.1016/j.eururo.2026.03.001

^{64}Cu-SAR-bisPSMA outperformed ^{68}Ga-PSMA-11 in all measured parameters

^{64}Cu-SAR-bisPSMA vs. ^{68}Ga-PSMA-11 demonstrated:

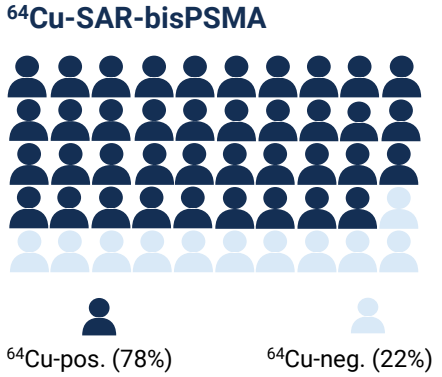
- Higher number of patients with a positive scan
- Higher true positive rate
- Higher number of lesions
- Higher number of anatomical regions with tracer uptake
- Higher rate of change in treatment plan
- Same scanning times (approximately 2 min/bed position)
  - *Median time between ^{68}Ga and ^{64}Cu scans: 2 days (IQR 1-8)*

"(…) whenever we can detect more lesions in the lower PSA ranges, we can eventually, as the Co-PSMA study shows, change the way we manage prostate cancer, (…)"

Dr Alberto Briganti, Editor-in-Chief, European Urology journal, European Urology Podcast*

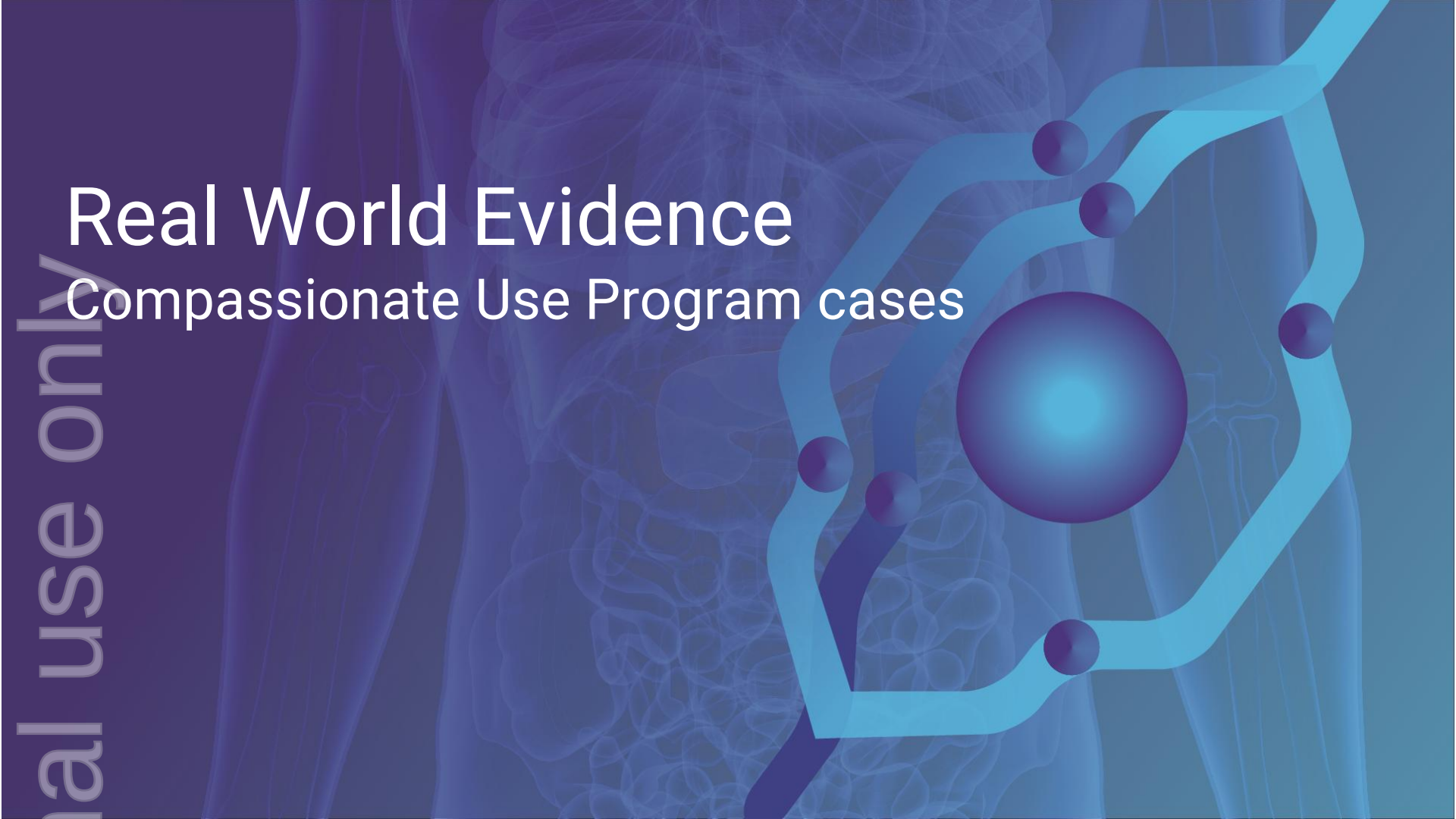
* 26-June-2026; https://www.youtube.com/watch?v=g4B7A6JxcZY

Participant-level detection of prostate cancer by tracer



Real World Evidence

Compassionate Use Program cases



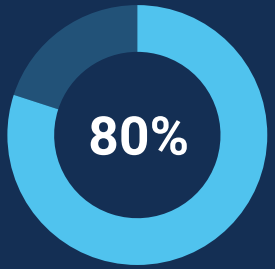
Closing the diagnostic gap: real-world ^{64}Cu-SAR-bisPSMA lesion detection after negative SOC PSMA PET

An unmet need persists for improved PSMA imaging, despite availability of SOC PSMA PET agents

Background

- Ten patients with BCR of PC and negative/equivocal SOC PSMA PET (^{68}Ga-PSMA-11; ^{18}F-DCFPyL) who accessed ^{64}Cu-SAR-bisPSMA via SAS/EAP were imaged
- Most recent PSA before ^{64}Cu-SAR-bisPSMA range: 0.10 – 13.3 ng/mL
- All patients received ~200 MBq of ^{64}Cu-SAR-bisPSMA, with PET imaging performed on the same-day and/or next-day post-injection
- Follow-up and monitoring for adverse events was undertaken

Key findings



8/10 patients had lesions detected with ^{64}Cu-SAR-bisPSMA

Total of 19 lesions identified on next-day imaging

Management change after positive ^{64}Cu-SAR-bisPSMA

Clinical treatment change	8/8
Targeted radiotherapy	4/8

Negative ^{64}Cu-SAR-bisPSMA findings occurred below the BCR-confirmatory threshold (<0.2 ng/mL)

PSA levels 0.10 and 0.19 ng/mL

Safety profile: one Grade 1 (mild) fatigue event, which resolved

Therapeutic Goods Administration (TGA, Australia) Special Access Scheme (SAS) and US FDA Expanded Access Program (EAP) cases; Data on file.

^{64}Cu-SAR-bisPSMA PET detects disease missed by Siemens Biograph Vision Quadra

Background

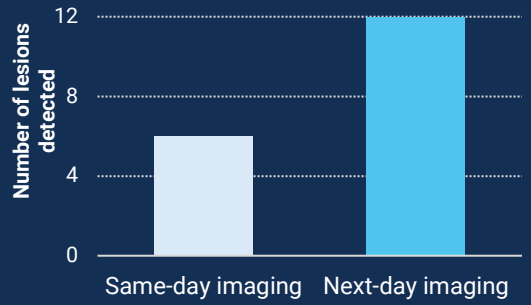
- Five patients with BCR of PC (PSA 0.3 – 13.3 ng/mL)
- Prior negative SOC PSMA PET/CT (^{68}Ga-PSMA-11 and/or ^{18}F-DCFPyL) using the Siemens Biograph Vision Quadra
- ^{64}Cu-SAR-bisPSMA PET/CT via compassionate use at 1-4 hours (same-day imaging) and 24-30 hours (next-day imaging) post-injection

Data on file. Image: Siemens Biograph Vision Quadra.
Source: https://www.siemens-healthineers.com/en-us/molecular-imaging/pet-ct/biograph-vision-quadra

Key findings

^{64}Cu-SAR-bisPSMA imaging was positive in all patients

2X more lesions detected on next-day (n=12) compared to same-day (n=6) imaging



Increased ^{64}Cu-SAR-bisPSMA uptake with delayed imaging

For the 6 lesions identified on both same-day and next-day:

	Same-day imaging	Next-day imaging
Mean SUVmax	4.0 ± 1.6	7.6 ± 3.3

^{64}Cu-SAR-bisPSMA led to treatment management changes in all 5 patients

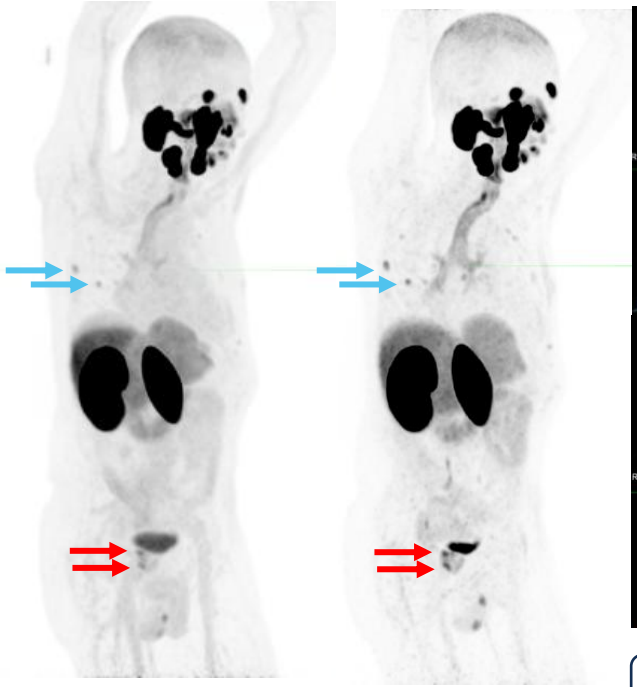
Case highlight: ^{64}Cu-SAR-bisPSMA detected lesions only 24 days after a negative ^{18}F-DCFPyL PSMA PET on Siemens Biograph Vision Quadra

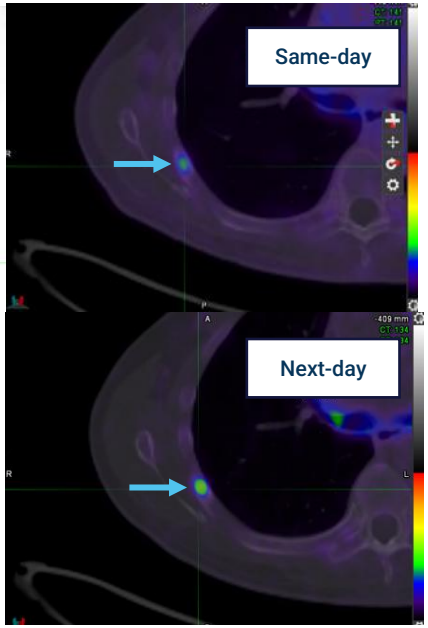
Patient with BCR Negative ^{18}F-DCFPyL*

24 days

^{64}Cu-SAR-bisPSMA detected 4 lesions

Same-day imaging | Next-day imaging





→ Localised recurrent lesion → Bone lesion

Change in management

*70 yr old patient with BCR following radical prostatectomy. Data on file.

Summary of real-world evidence cases

^{64}Cu-SAR-bisPSMA: confirming outcomes in real-world cases seen in the clinical trial setting

- There is a **need for a more sensitive PSMA PET agent** despite the availability of current SOC PET agents
- **^{64}Cu-SAR-bisPSMA identified lesions in 8 out of 10 patients** whose SOC PSMA PET was **negative or equivocal**
- Lesions were missed or remained equivocal with SOC PSMA PET agents, **even when delayed imaging was performed on advanced cameras such as the Biograph Vision Quadra**
- **^{64}Cu-SAR-bisPSMA identified lesions in all patients** who had a negative/equivocal scan using SOC PMSA PET agents **imaged on the Biograph Vision Quadra**
- ^{64}Cu-SAR-bisPSMA findings **changed clinical management in every patient with a positive scan**

CLARITY PHARMACEUTICALS

Data on file.

Separating signal from noise: addressing competitive claims

Lesion detection and clinical impact

Competitive claim	What the data show	Takeaway
Co-PSMA population is only relevant to a subset of the market because value depends on 24-hour imaging	• Same-day imaging remains clinically relevant: **Co-PSMA showed similar same-day detection rate with ^{64}Cu-SAR-bisPSMA (34%) vs. ^{68}Ga-PSMA-11 (36%), while PROPELLER showed 2-3x higher lesion uptake and contrast and 1.3x more lesions vs. ^{68}Ga-PSMA-11** • **Delayed imaging adds optional clinical value by allowing higher lesion uptake and background washout**, supporting improved lesion detection • **Other Clarity trials do not impose an upper baseline PSA limit**, supporting applicability across broader clinical settings	**Flexible imaging window supports both routine workflow and enhanced detection when clinically valuable**
Change in management data are survey-based and therefore not meaningful evidence	• Management impact questionnaires are **recognised endpoints in diagnostic imaging studies** because the purpose of imaging is to inform **treatment decisions** • ^{64}Cu-SAR-bisPSMA led to substantial management impact: **44-48% of participants had a change in planned management** (Co-PSMA and COBRA) • In Co-PSMA, **active management was planned in 90% of cases following ^{64}Cu-SAR-bisPSMA PET vs. 66% after ^{68}Ga-PSMA-11 PET**	**Clinical impact is demonstrated by measurable changes in planned treatment, not just lesion counts**
Detecting more lesions has limited value; the real value is moving from no detection to some detection	• **This claim disregards the role of accurate staging in personalised prostate cancer care**, including decisions between metastasis-directed therapy and systemic therapy • In Co-PSMA, **treatment changes included altered radiation fields, stereotactic body radiotherapy and added androgen deprivation therapy** • Regarding the point of “from ‘no’ to ‘some’ lesions”, **^{64}Cu-SAR-bisPSMA more than doubled the number of participants with a positive scan: 78% vs. 36% with ^{68}Ga-PSMA-11** (Co-PSMA)	**More accurate detection can change both whether patients are treated and how treatment is targeted**

Data on file.

Separating signal from noise: addressing competitive claims

Camera technology and clinical workflow

Competitive claim	What the data show	Takeaway
Improved camera technology makes the difference, not the agent	• Published prospective evidence supporting improved detection using current PSMA PET agents with advanced cameras, particularly at low PSA, remains limited to support this claim • Real-world cases show SOC PSMA PET can remain negative/equivocal even when advanced cameras are used; ^{64}Cu-SAR-bisPSMA detected recurrent disease in a series of similar cases (to be presented at EANM 2026) • If camera technology improves lesion detection, it may also further enhance the performance of ^{64}Cu-SAR-bisPSMA	**The available evidence supports agent differentiation rather than attributing results solely to camera technology**
Next-day imaging will not be a major part of the market	• ^{64}Cu-SAR-bisPSMA offers next-day imaging leading to higher lesion uptake and background washout enabling improve detection rate and the detection of small lesions • The value proposition is flexibility with high sensitivity: patients can be imaged on either day, but next-day imaging provides higher diagnostic confidence • This positions next-day imaging as a clinical advantage rather than a workflow limitation	**Delayed imaging is an option that can extend clinical utility, not a restriction on use**
Longer scans create a throughput disadvantage, with next-day imaging creating workflow challenges	• In Co-PSMA, camera time was the same for ^{64}Cu-SAR-bisPSMA and ^{68}Ga-PSMA-11: 2 minutes per bed position • Clinicians have reported that an optimised clinical workflow can actually improve operational efficiency, with patients simply attending for injection on one day, and returning for imaging on the following day – streamlining back-to-back (in sequence) scanning sessions	**The workflow argument is addressable, and the cited Co-PSMA scan time with potential increased operational efficiency does not support a major throughput disadvantage**

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Data on file.

Separating signal from noise: addressing competitive claims

The value of delayed imaging

Competitive claim	What the data show	Takeaway
The value is only at the late imaging timepoint	• Co-PSMA showed that **^{64}Cu-SAR-bisPSMA at 1 hour performed similarly to ^{68}Ga-PSMA-11** (detection rate 34% vs. 36%, respectively) • PROPELLER showed **improved same-day imaging performance at 2-4 hours, with 1.3x more lesions identified vs. ^{68}Ga-PSMA-11** • PROPELLER also showed **lesion uptake and contrast were 2-3x higher** for ^{64}Cu-SAR-bisPSMA vs. ^{68}Ga-PSMA-11. • COBRA showed that the **detection rate on same-day ^{64}Cu-SAR-bisPSMA PET was 70% vs. 60% for SOC PSMA PET**, which was performed up to 6 months after the ^{64}Cu-SAR-bisPSMA PET (indicating the ability of ^{64}Cu-SAR-bisPSMA to detect recurrent disease earlier) • This demonstrates that **differentiation is not limited to 24-hour imaging**	**The evidence supports clinical flexibility, with same-day proven performance and added value from next-day imaging**
Delayed imaging is a narrow niche rather than a broad advantage	• **COBRA and Co-PSMA support improved lesion detection with next-day ^{64}Cu-SAR-bisPSMA imaging** • **^{64}Cu-SAR-bisPSMA identified lesions in 78% of participants vs. 36% with ^{68}Ga-PSMA-11** (Co-PSMA) • **The true positive rate was 71% for ^{64}Cu-SAR-bisPSMA vs. 29% for ^{68}Ga-PSMA-11** (Co-PSMA) • COBRA showed that the **detection rate on next-day imaging was 90% vs. 60% for SOC PSMA PET**, which was performed up to 6 months after the ^{64}Cu-SAR-bisPSMA PET (indicating the ability of ^{64}Cu-SAR-bisPSMA to detect recurrent disease earlier) • Across the evidence base, **next-day imaging adds clinical value with further improved diagnostic performance**	**Next-day imaging is positioned as a differentiating clinical option with solid evidence to improve diagnostic performance**

Clinical use only

CLARITY PHARMACEUTICALS

Data on file.

Separating signal from noise: addressing competitive claims

Differentiation and market uptake

Competitive claim	What the data show	Takeaway
Clarity will be late (5th) to market, making meaningful share gains difficult	• The **current competitive landscape has limited differentiation among approved PSMA PET agents** with similar structural and isotopic characteristics • **Commercial uptake is not determined by order of entry alone; clinical value and differentiation** can change adoption dynamics • ^{64}Cu-SAR-bisPSMA is positioned as a **differentiated agent, rather than another similar ("me-too") PSMA PET product** • The differentiators **include dimeric PSMA targeting, longer copper-64 half-life, sarcophagine chelator, extended shelf-life, wider imaging window and broad geographic coverage** • The clinical proposition is supported by robust evidence from **PROPELLER, COBRA and Co-PSMA** • **Phase III CLARIFY and AMPLIFY are intended to generate the pivotal evidence** to support broad clinical adoption	**Commercial success is driven by clinical differentiation and value, not simply order of market entry**

	^{64}Cu-SAR-bisPSMA	^{68}Ga-PSMA-11[1,2*]	^{18}F-DCFPyL[3,4*]	^{18}F-rhPSMA-7.3[5,6*]
Targeting moiety	Dimer targeting PSMA	Monomer targeting PSMA	Monomer targeting PSMA	Monomer targeting PSMA
Isotope half-life	^{64}Cu (12.7 h)	^{68}Ga (1.1 h)	^{18}F (1.8 h)	^{18}F (1.8 h)
Product shelf-life	Up to 48 h	6 h	10 h	10 h
Imaging window (post-administration)	1 to 30 hrs	50 to 100 min	1 h	1 h
Sensitivity	CLARIFY	40% (prespecified endpoint not met)	40% (prespecified endpoint not met)	27% (prespecified endpoint not met)
Specificity		95% (prespecified endpoint not met)	98%	95%

Data on file. 1. Hope T et al., JAMA Oncol. 2021;7;(11):1635-1642. 2, 4 and 6: FDA-approved Prescribing Information. Accessed on 20 June 2026. 3. Pienta KJ et al Osprey J Urol. 2021;206(1):52-61. 5. Surasi DS el al LIGHTHOUSE Eur Urol 2023;84:361-370. * Primary endpoints related to the registrational trials in the pre-prostatectomy setting respective to each product. Source: FDA Center for Drug Evaluation and Research, Multi-Discipline Review Differences in study design and patient populations preclude direct cross-trial comparisons.

High demand for effective diagnostic PSMA PET agents that lead to high patient impact

"I am a high-volume prostate cancer surgeon, with many of my patients in the higher risk category. I have been operating on these patients for many years and routinely do nodal dissection. ***I have not found Ga 68 PET to be particularly helpful and am interested in participating in your Cu 64 trial.*** *I understand that there is a centre close by involved already, but I would like to explore recruiting and treating in the private sector where I am based."*

Australian treating clinician

"The results (of the ^{64}Cu-SAR-bisPSMA PET) were beyond my expectations. Three tumours were found and I underwent targeted external beam radiation. *(…) I am currently symptom-free and hope to remain like this for a long time. It certainly demonstrates the importance of this agent for patients like me."*

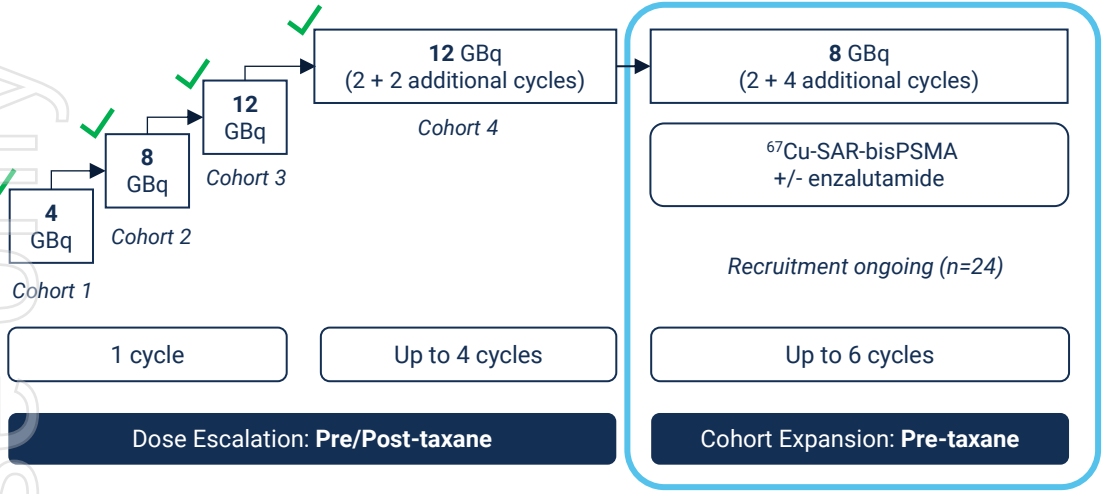
Patient in BCR, with a negative SOC PSMA PET using state-of-the-art camera

^{67}Cu-SAR-bisPSMA therapy in PC

SECuRE

SECuRE Phase I/IIa trial: recruiting

Phase I/IIa, dose-escalation, dose-finding and cohort expansion theranostic trial of $^{64/67}$Cu-SAR-bisPSMA for identification and treatment of participants with mCRPC



Dose escalation phase: completed

Cohort expansion phase: currently recruiting

Patient population

- Patients with progressive mCRPC despite previous treatment with ADT and ARPI
- Patients with PSMA-expressing lesions per ^{64}Cu-SAR-bisPSMA PET/CT

A subset of participants in the Cohort Expansion phase will receive ^{67}Cu-SAR-bisPSMA with enzalutamide (an ARPI)

Key primary objectives

- Safety and tolerability of $^{64/67}$Cu-SAR-bisPSMA
- To determine the maximum tolerated or maximum feasible single dose as well as the recommended dose for two administrations of ^{67}Cu-SAR-bisPSMA
- Efficacy in terms of PSA and radiographic response

Additional eligibility criteria apply. ADT: androgen deprivation therapy. Investigational products only. Not approved by the FDA. For scientific exchange and non-promotional purposes only. ClinicalTrials.gov identifier: NCT04868604.

Patient characteristics: heavily pre-treated patient group with most having bone metastasis

	Cohort 1 (N=6)	Cohort 2 (N=3)	Cohort 3 (N=6)	Cohort 4 (N=7)	Cohort Expansion (N=16)	Total (N=38)
Location of Metastases						
Bone	6 (100%)	2 (66.7%)	4 (66.7%)	5 (71.4%)	10 (62.5%)	27 (71.1%)
Lymph Node	1 (16.7%)	2 (66.7%)	4 (66.7%)	4 (57.1%)	6 (37.5%)	17 (44.7%)
Other	0	0	1 (16.7%)	0	2 (12.5%)	3 (7.9%)
Baseline* PSA (ng/mL)						
Mean (SD)	1532.27 (3029.7)	104.28 (155.7)	368.84 (547.9)	606.65 (1351.1)	38.71 (47.2)	449.39 (1396.5)
Median	333.73	29.33	110.96	42.00	22.01	37.34
Min-Max	0.7-7684.2	0.3-283.2	34.3-1329.5	3.9-3655.8	0.0-156.7	0.0-7684.2
Number of Previous Anticancer Regimens						
2	0	0	0	0	1 (6.3%)	1 (2.6%)
3	0	0	0	0	1 (6.3%)	1 (2.6%)
4	0	1 (33.3%)	0	0	1 (6.3%)	2 (5.3%)
5	0	0	0	0	1 (6.3%)	1 (2.6%)
>5	6 (100%)	2 (66.7%)	6 (100%)	7 (100%)	12 (75.0%)	33 (86.8%)

Preliminary analysis. Final results are pending completion of the trial. ClinicalTrials.gov identifier: NCT04868604. Data cut-off: 20 Jul 2026. Data on file.

Safety overview: most adverse events were mild/moderate, indicating a favourable safety profile of ^{67}Cu-SAR-bisPSMA

SECURE

Most common related adverse events (AEs) regardless of severity

	Cohort Expansion (N=16)	All Participants at 8 GBq cycles (N=19)
n (%)	Grades 1/2	Grades 1/2
Dry mouth	8 (50%)	9 (47)%
Nausea	8 (50%)	8 (42%)
Anaemia	4 (25%)	4 (21)%
Neutrophil count decrease	4 (25%)	4 (21%)
Fatigue	4 (25%)	5 (26%)

Among participants who received 8 GBq cycles (Cohort 2 and Cohort Expansion), the most common related AEs were gastrointestinal and haematological disorders, with the majority being mild (Grade 1) and transient

- Only 2 related Grade 3 AEs were reported in one participant (lymphocyte and white blood cell count decreases, 5%)
- No Grade ≥4 were reported
- Participants receiving 8 GBq dose generally developed a lower prevalence and severity of related AEs compared to the overall trial population

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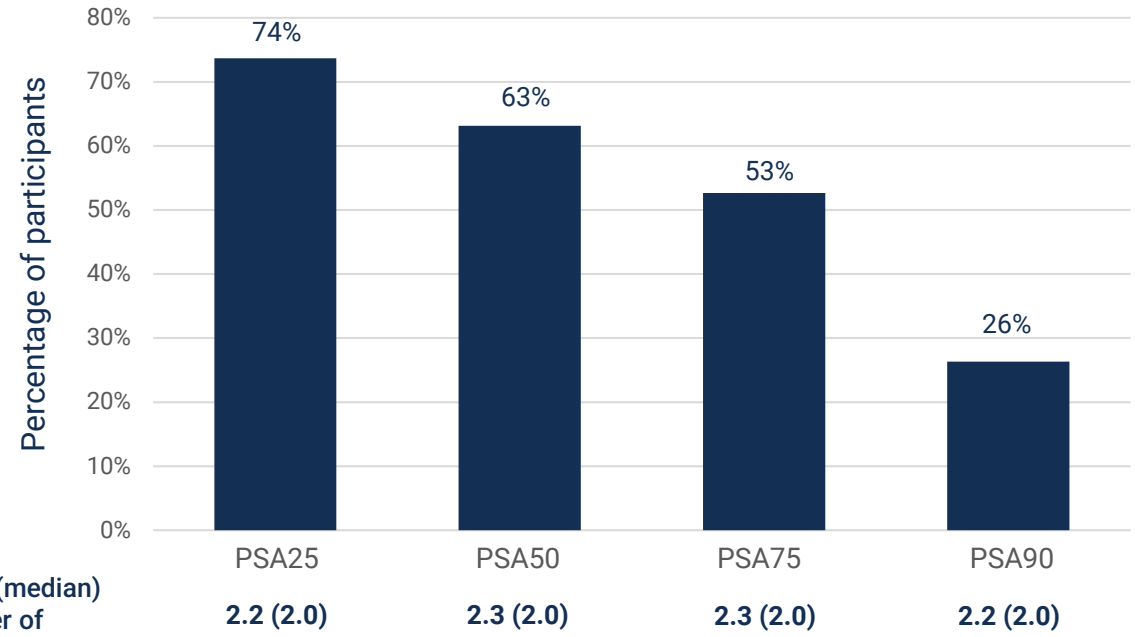
The table shows the 5 most common related AEs from the Cohort Expansion Phase. Correspondent prevalence and severity of the same AEs are shown for all participants who received 8 GBq cycles. Preliminary analysis. Final results are pending completion of the trial. ClinicalTrials.gov identifier: NCT04868604. Data cut-off: 20 Jul 2026. Data on file.

High PSA response rates across 8 GBq participants (Cohort 2 + Cohort Expansion)

SECURE

Pooled 8 GBq
(Dose Escalation + Cohort Expansion)

Response rates across participants (8 GBq cycles)



PSA response categories and mean number of treatment cycles

Key response rates

63%
PSA50 response

26%
PSA90 response

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Preliminary analysis. Final results are pending completion of the trial. ClinicalTrials.gov identifier: NCT04868604. Data cut-off: 20 Jul 2026. Data on file.

^{67}Cu-SAR-bisPSMA 8 GBq leads to PSA reductions and complete responses/undetectable disease in mCRPC participants

SECURE

A total of 19 participants have received ^{67}Cu-SAR-bisPSMA at 8 GBq (Cohort 2 and Cohort Expansion phase), which demonstrated anti-tumour effect and favourable safety profile

PSA50 in **63%** of participants

PSA90 in **26%** of participants

CR/Undetectable disease in **31%** of evaluable participants*

Treatment cycles

74%

received up to two cycles of 8 GBq of ^{67}Cu-SAR-bisPSMA

Median:	2.0
Range:	1 – 4
Mean ± SD:	2.1 ± 1.0

CR/undetectable disease

5 of 16

evaluable participants (31%) in the combined 8 GBq cohorts

Total of 7 participants achieving CR/undetectable disease across the overall ^{67}Cu-SAR-bisPSMA program, all dose levels

Disease control

81%

of evaluable participants (n=16) for radiographic assessment

Complete response or undetectable disease:	31% (n=5)
Stable disease:	50% (n=8)

Safety profile

Most related adverse events were mild (Grade 1) and transient†

Majority were gastrointestinal and haematological disorders. Two Grade 3 events (lymphocyte and white blood cell count decreases) in 1 participant. No Grade ≥4 related events were reported.

CR: complete response. *CR/undetectable disease represents no evidence of disease by RECIST, bone scan and/or PSA assessment, which were evaluable in 16 out of 19 participants (evaluable for radiographic assessment). Total of 7 participants with CR/undetectable disease include one participant from Cohort 2 (who achieved CR following a second cycle of ^{67}Cu-SAR-bisPSMA under Expanded Access Program), 2 from Cohort 4 and 4 from the Cohort Expansion phase. Disease control: CR/undetectable disease + partial response + stable disease. †Most frequently reported related AEs (n=19): dry mouth 9 (47%), nausea 8 (42%), fatigue 5 (26%), anaemia 4 (21%), decreased neutrophil count 4 (21%). Preliminary analysis. Final results are pending the completion of the trial. ClinicalTrials.gov identifier: NCT04868604. Data cut-off: 20 Jul 2026. Data on file.

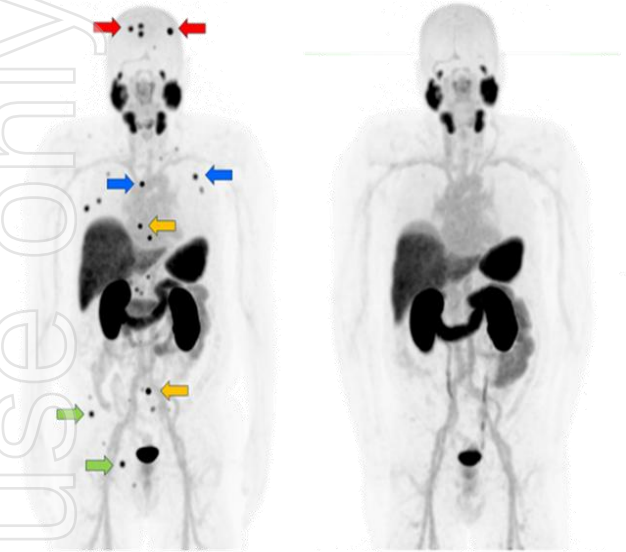
^{67}Cu-SAR-bisPSMA 8 GBq leads to undetectable disease in mCRPC (assessed by PSA and imaging)

SECURE

Cohort Expansion

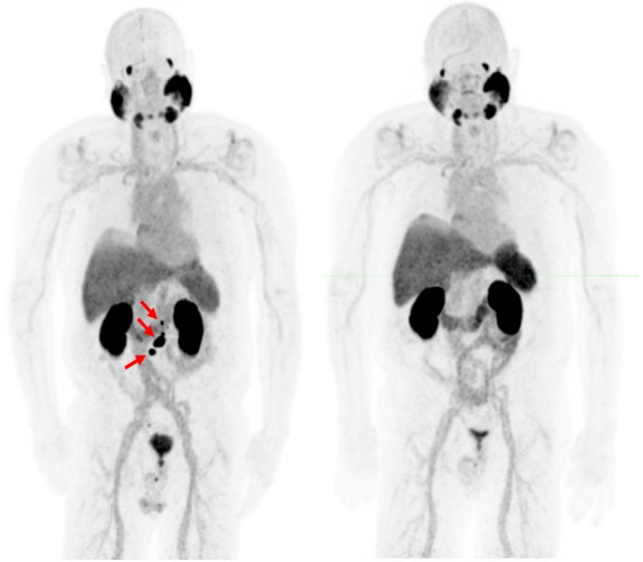
Patient A

Baseline *(Bone metastasis)*	Post-^{67}Cu-SAR-bisPSMA (2 x 8 GBq)



Patient B

Baseline *(Nodal metastasis)*	Post-^{67}Cu-SAR-bisPSMA (2 x 8 GBq)



- No evidence of disease reported following the administration of 3 or fewer cycles of ^{67}Cu-SAR-bisPSMA
- All adverse reactions were mild or moderate
- Participants remained with no evidence of disease at last follow-up

Patient A: 64-year-old man with bone metastases. Coloured arrows **(left image)** indicate metastatic bone lesions within each region: red – skull; blue – ribs and sternum; orange – spine; green – pelvis. Related AEs: mostly transient, mild (Grade 1) and non-haematological AEs were reported. The participant reported having excellent quality of life following the treatment. Total number of cycles administered: 4. **Second image from the left**: no evidence of disease. **Patient B:** 76-year-old man with metastatic nodal lesions (arrows, **third image from left, "Baseline"**). **Left image**: no evidence of disease. Related AEs included altered taste, dry eyes, eye pain, salivary gland soreness and anaemia (all resolved except anaemia). No renal AEs have been reported to date. Images are shown as maximum intensity projections. Last follow-up for both patients:

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Preliminary analysis. Final results are pending completion of the trial. ClinicalTrials.gov identifier: NCT04868604. Data cut-off: 20 Jul 2026. Data on file.

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^{67}Cu-SAR-bisPSMA 8 GBq cycles show strong anti-tumour efficacy with a favourable safety profile in mCRPC

- High PSA response rates at 8 GBq, with **PSA reductions ≥25%, ≥50%, ≥75% and ≥90% observed in 74%, 63%, 53% and 26% of participants**, respectively
- Evidence of deep anti-tumour activity, including **complete response/undetectable disease in 31% (5/16 evaluable participants for radiographic assessment)** and **disease control in 81%** of those receiving 8 GBq
- **Seven participants across the overall ^{67}Cu-SAR-bisPSMA program achieved complete response and/or undetectable disease**
- **Favourable safety profile** with most treatment-related adverse events being Grade 1 and transient, no related Grade ≥4 adverse events reported, and only two related Grade 3 events occurring in a single participant

Preliminary analysis. Final results are pending completion of the trial. ClinicalTrials.gov identifier: NCT04868604. Data cut-off: 20 Jul 2026. Data on file.

Highly experienced team

Dr Alan Taylor
Executive Chairperson

Michelle Parker
CEO and MD

Dr Colin Biggin
Chief Operating Officer

Eva Lengyelova
EVP – Clinical Development

Shaemus Gleason
EVP - Operations

Dr Othon Gervasio
Chief Medical Officer

Dr Ellen van Dam
Chief Scientific Officer

Mary Bennett
Head of People and Culture

Robert Vickery
Company Secretary

David Green
Chief Financial Officer

Juliane Foley
VP Regulatory Affairs

Chris Horvath
Chief Commercial Officer

Clarity's management team has a diverse and in-depth level of expertise spanning corporate finance, management, clinical, operations, commercialisation and industry

- Development, approval and launch of 1st approved radiopharmaceutical therapy product for prostate cancer (Xofigo)
- Decades of experience spanning across science, nuclear medicine/PET and pharmaceutical industries
- Investment banking experience focused on the life sciences sector

Thank you