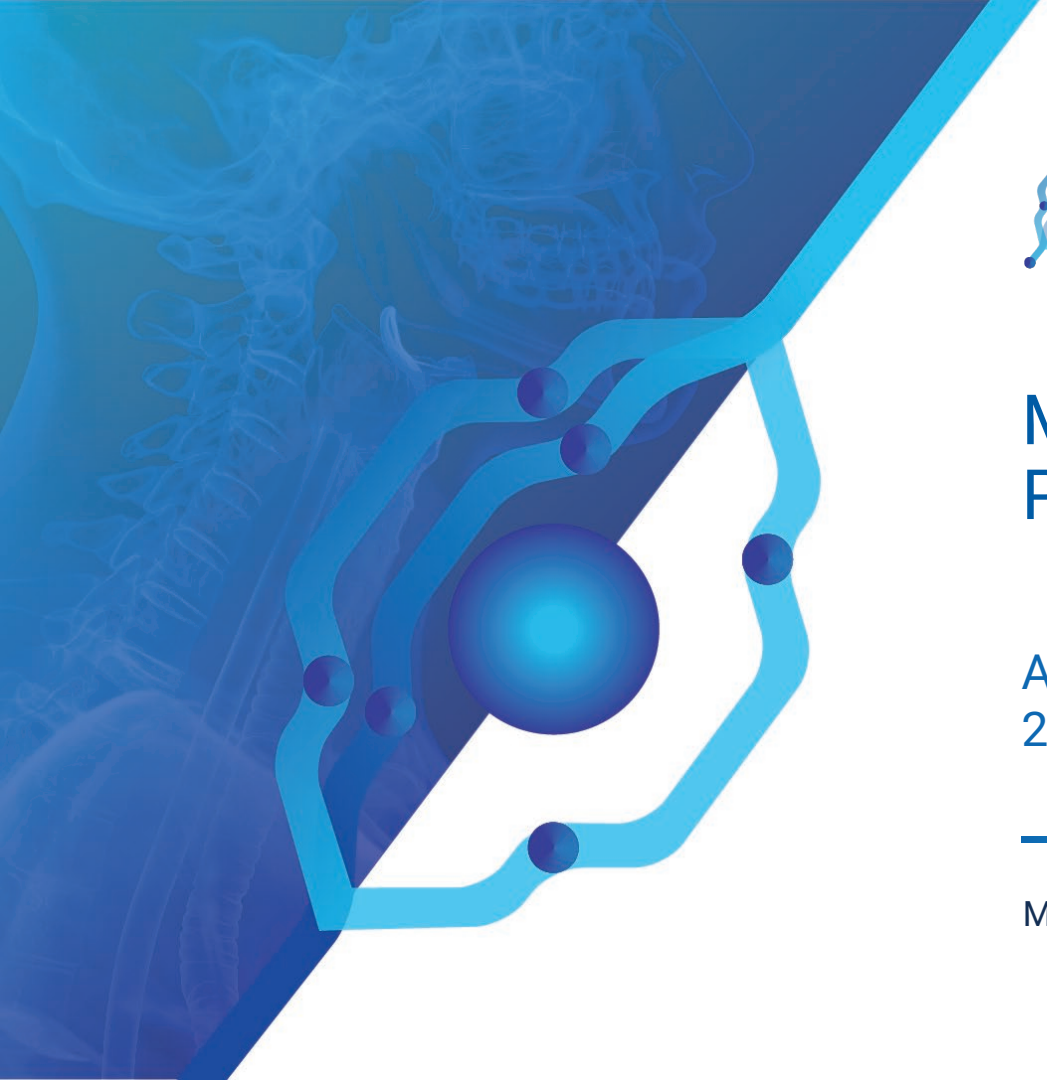

CLARITY PHARMACEUTICALS

Managing Director's Presentation

Annual General Meeting
25 November 2026

Ms Michelle Parker

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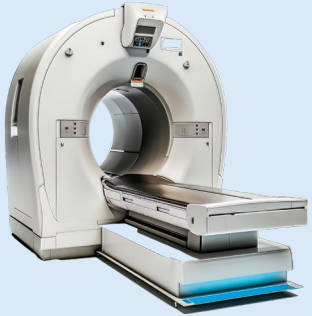
Products
All products discussed in this presentation are investigational only and are not approved by the US Food and Drug Administration (FDA) or Therapeutic Goods Authority (TGA, Australia).

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

Clarity’s ultimate mission is to improve treatment outcomes for people with cancer

Summary of key achievements

PSMA Diagnostics

^{64}Cu-SAR-bisPSMA

AMPLIFY Phase III completed recruitment and all patient follow-up

CLARIFY Phase III completed recruitment

Co-PSMA head-to-head trial with intra-patient comparisons selected as Editor's Choice article in European Urology (29.7 impact factor) and presented at the EANM and EAU Congresses

Breakthrough Therapy designation granted by the US FDA for BCR

PSMA Therapy

^{67}Cu-SAR-bisPSMA

SECuRE trial progressed with completion of recruitment of the Main Group; recruitment ongoing in the enzalutamide group

High response rates with favourable safety profile

31% of evaluable participants who received 8 GBq ^{67}Cu-SAR-bisPSMA cycles achieved a complete response (assessed by RECIST) or undetectable disease (assessed by bone scan and/or PSA)

SARTATE Dx

^{64}Cu-SARTATE

Successful end-of-phase meeting with the US FDA with positive guidance

Phase III trial in planning

Operational Excellence

Technical Operations: Advancing clinical and commercial manufacturing and supply chain capabilities to prepare for product launch

People and Culture: Growing and developing Clarity's team and welcoming new Senior Executive Team members

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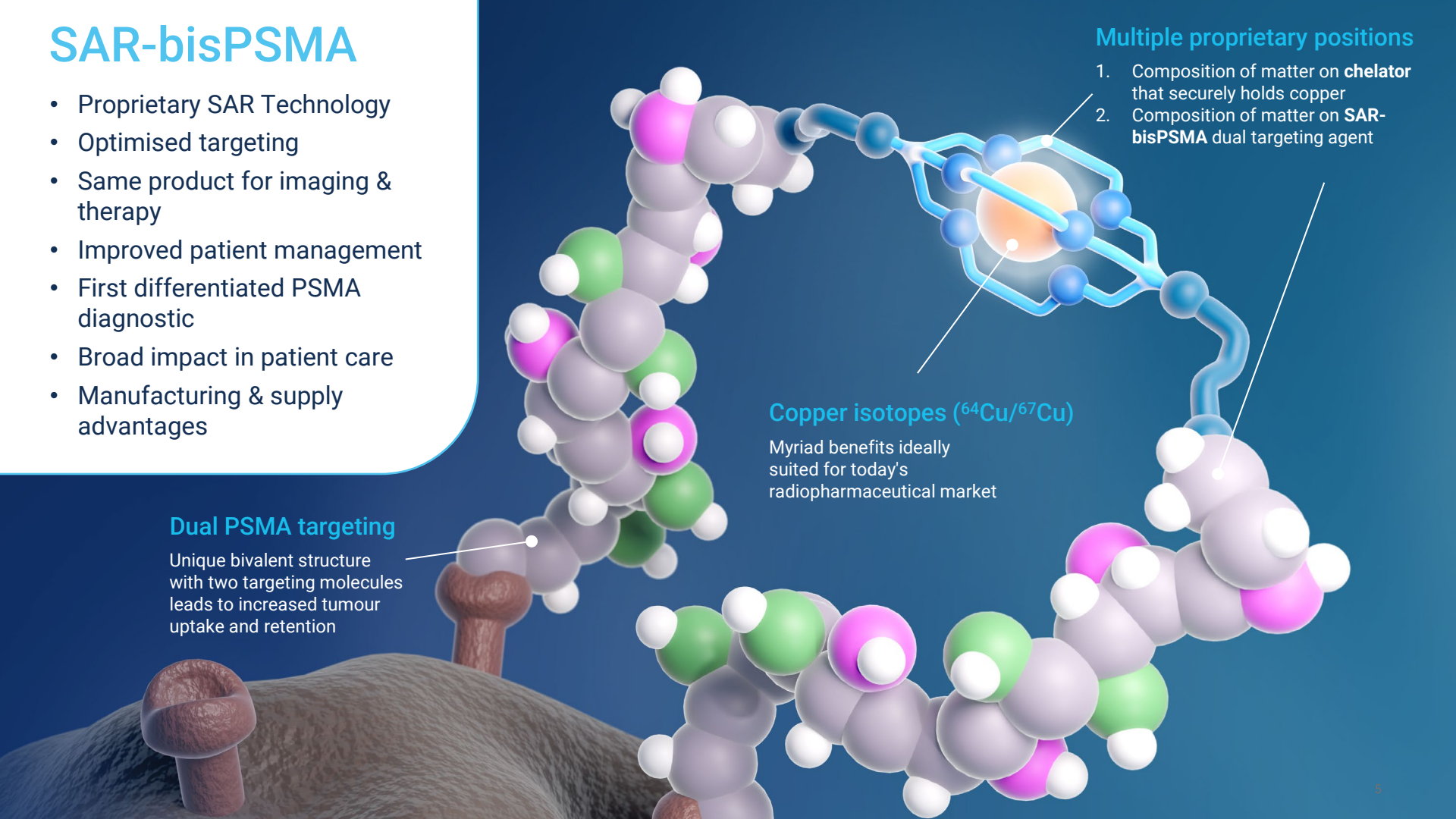
EAU: European Association of Urology; EANM: European Association of Nuclear Medicine; BCR: biochemical recurrence; US FDA: United States Food and Drug Administration; PSA: prostate-specific antigen; RECIST: Response Evaluation Criteria in Solid Tumors 1.1

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



Multiple 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 bivalent structure with two targeting molecules leads to increased tumour uptake and retention

Australian innovation challenging the PSMA PET standard

	^{64}Cu-SAR-bisPSMA	^{68}Ga-PSMA-11[1-3]*	^{18}F-DCFPyL[4-6]*	^{18}F-rhPSMA-7.3[7-9]*
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	Bivalent PSMA targeting	Monovalent PSMA targeting	Monovalent PSMA targeting	Monovalent PSMA targeting
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 threshold not met)	38% (prespecified endpoint threshold not met)	27% (prespecified endpoint threshold not met)
Patient-level detection rate (biochemical recurrence)	AMPLIFY	Overall: 75% PSA <0.5 ng/mL: 38%	Overall: 59 – 66% PSA <0.5 ng/mL: 25 – 48%	Overall: 83% PSA <0.5 ng/mL: 64%

⊘ 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[5]

Note: Not a head-to-head comparison. Cross-study comparisons are limited by differences in study design, patient populations, endpoints and methodology.
*Primary endpoints in the pre-prostatectomy and biochemical recurrence settings based on each product's registrational trials and the corresponding FDA Center for Drug Evaluation and Research, Multi-Discipline Review.

1. Hope T, et al. JAMA Oncol. 2021;7;(11):1635-1642. 2. Gallium Ga 68 gozetotide injection. Prescribing Information. UCLA Biomedical Cyclotron Facility; 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/212642s002lbl.pdf. 3. Fendler WP, Calais J, Eiber M, et al. JAMA Oncol. 2019;5(6):856-863. 4. Pienta KJ, et al. J Urol. 2021;206(1):52-61. 5. PYLARIFY TRUVU® (piflufolastat F 18) prescribing information. FDA; 2026. https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/220089Orig1s000lbl.pdf. 6. Morris MJ, et al. Clin Cancer Res. 2021;27(13):3674-3682. 7. Surasi DS, el al. Eur Urol. 2023;84:361-370. 8. POSLUMA® (flotufolastat F 18) prescribing information. FDA; 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216023s000lbl.pdf. 9. Jani AB, et al. J Urol. 2023;210(2):299-311.
^{64}Cu-SAR-bisPSMA data on file.

First ever Breakthrough Therapy designation in PSMA PET and three Fast Track Designations

Fewer than half of requests across all therapeutic areas are granted Breakthrough Therapy designations. They are focused on expediting the development and review of products intended to treat a serious condition and fill an unmet medical need.

Breakthrough Therapy designation

^{64}Cu-SAR-bisPSMA

Patients with prostate cancer with **suspected recurrence** based on elevated serum PSA level

Fast Track designation

^{64}Cu-SAR-bisPSMA

Patients with **biochemical recurrence** of prostate cancer following definitive therapy

Fast Track designation

^{64}Cu-SAR-bisPSMA

Patients with suspected metastasis who are **candidates for initial definitive therapy**

Fast Track designation

^{67}Cu-SAR-bisPSMA

Treatment of adult patients with PSMA-positive **mCRPC** who have been previously treated with an ARPI

Fast Track: can be granted on early-stage or non-clinical data

Breakthrough Therapy: requires preliminary clinical evidence of considerable additional benefit over available products

Priority Review: Breakthrough Therapy designation signals potential eligibility (shortened FDA review timeline)

U.S. Food and Drug Administration. *Expedited Programs for Serious Conditions: Drugs and Biologics. Guidance for Industry*. Additional criteria apply. https://www.fda.gov/media/86377/download. Breakthrough Therapy designation requests: https://www.fda.gov/drugs/ind-activity/breakthrough-therapy-designation-requests. ARPI: androgen receptor pathway inhibitor; mCRPC: metastatic castration-resistant prostate cancer; PET: positron emission tomography

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SAR-bisPSMA: Next-generation products for prostate cancer

Extensive clinical development program in the pre-prostatectomy and biochemical recurrence settings

Ongoing trials

CLARIFY - Phase III in pre-prostatectomy[1]

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

AMPLIFY – Phase III in BCR[2]

- Registrational Phase III imaging trial with ^{64}Cu-SAR-bisPSMA in prostate cancer patients with BCR
- Recruitment completed and all participants' follow-ups completed

SECuRE - Phase I/IIa in mCRPC[3]

- Theranostic trial for treatment of patients with mCRPC with ^{67}Cu-SAR-bisPSMA
- Dose Escalation (Phase I) successfully completed recruitment
- Cohort Expansion (Phase II) recruitment closed in the Main Group; recruitment ongoing in the Enzalutamide Group

Completed trials

PROPELLER – Phase I in pre-prostatectomy[4]

- 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[5]

- 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[6]

- 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 published

1. NCT06056830. 2. NCT06970847. 3. NCT04868604. 4. NCT04839367. 5. NCT05249127. 6. NCT06907641

CLARIFY and AMPLIFY: Registrational Phase III trials designed to measure diagnostic performance against defined reference standards

CLARIFY

Topline data 1HCY2027

Pre-prostatectomy, high-risk prostate cancer (n=383)

REFERENCE STANDARD

Histopathology of surgically removed pelvic lymph nodes to verify ^{64}Cu-SAR-bisPSMA PET/CT findings

CO-PRIMARY ENDPOINTS

- Sensitivity
- Specificity

Same-day and next-day imaging assessed independently

AMPLIFY

Topline data 1HCY2027

Biochemical recurrence (n=232)

REFERENCE STANDARD

Composite reference standard: histopathology, PSA levels after loco-regional therapy or follow-up conventional scans

CO-PRIMARY ENDPOINTS

- Participant-level correct detection rate
- Region-level positive predictive value

Same-day and next-day imaging assessed independently

Exploratory endpoints include intra-patient, head-to-head comparisons of the diagnostic performance of ^{64}Cu-SAR-bisPSMA vs. SOC PSMA PET agents

Investigational products only. Not approved by the FDA. For scientific exchange and non-promotional purposes only. CT: computed tomography.
ClinicalTrials.gov identifier: CLARIFY (NCT06056830); AMPLIFY (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

PRIMARY OBJECTIVE MET — **HEAD-TO-HEAD**

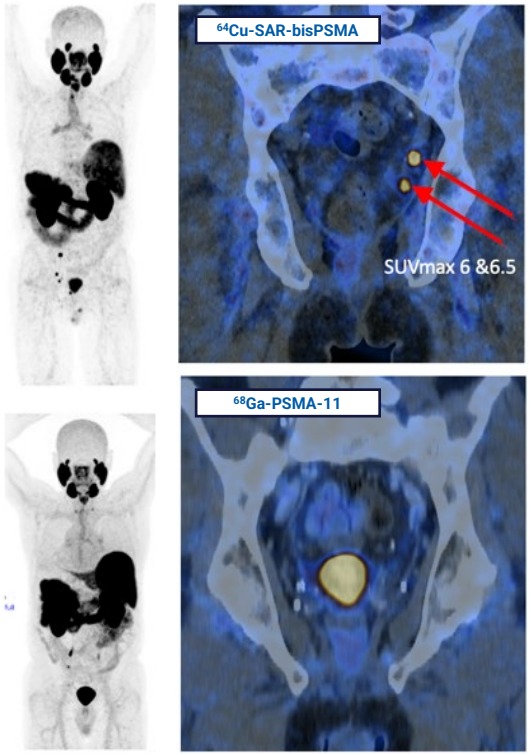
To compare the number of lesions per participant

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

Next-day ^{64}Cu-SAR-bisPSMA PET detected **2.6x more lesions per participant** than ^{68}Ga-PSMA-11 ($p < 0.0001$)

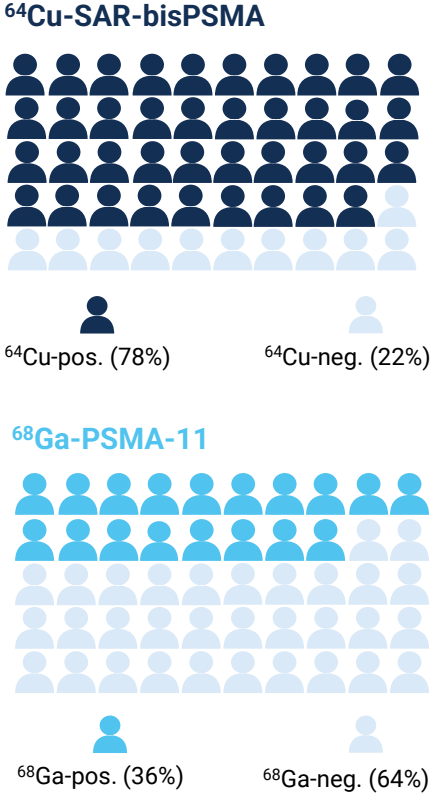
90% of patients (45/50) had an active treatment plan based on ^{64}Cu-SAR-bisPSMA scans *(vs. 66% with ^{68}Ga-PSMA-11)*

Higher total number of lesions and true positive rate with next-day ^{64}Cu-SAR-bisPSMA PET vs. ^{68}Ga-PSMA-11 *(63 vs. 24 and 71% vs. 29%, respectively)*



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

Participant-level detection of prostate cancer by tracer



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.

SECuRE Phase I/IIa trial: Main Group recruited

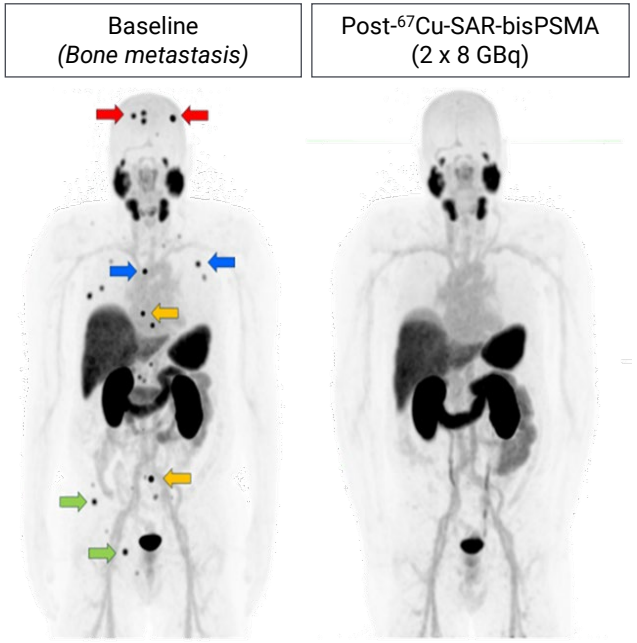
SECuRE

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

- Recruitment completed in the Main Group; recruitment ongoing in the Enzalutamide Group.
- 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% of participants** (5/16 evaluable participants for radiographic assessment) and **disease control in 81%** of those treated at 8 GBq dose levels
- **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

Key response rates

63%	26%	31%
PSA50 response	PSA90 response	CR/undetectable disease



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.

Preliminary analysis. CR/undetectable disease: complete response (assessed by RECIST) or undetectable disease (assessed by bone scan and/or PSA) in evaluable participants. 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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SARTATE

SARTATE is a next-generation, highly targeted theranostic radiopharmaceutical. It is being developed for diagnosing, staging and subsequently treating cancers that express somatostatin receptor 2 (SSTR2). Clarity is prioritising the development of SARTATE into early commercialisation with a focus on neuroendocrine tumours (NETs) imaging in the first instance.

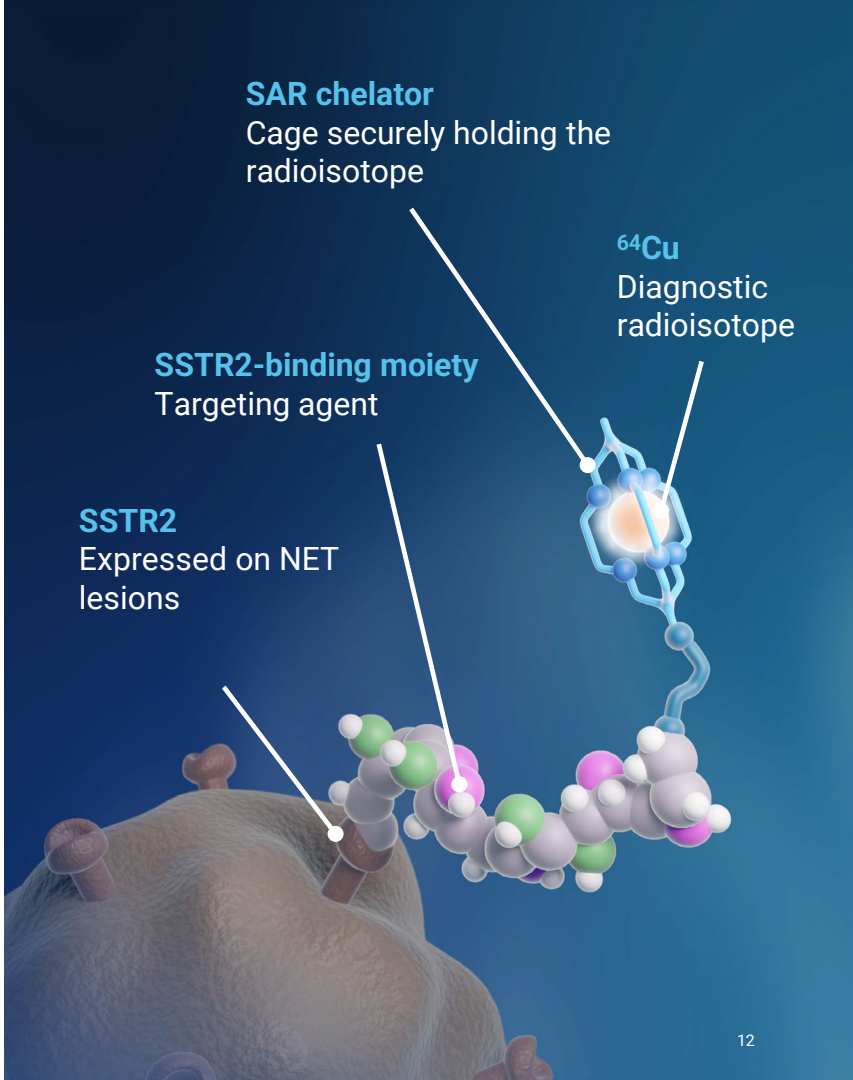
Clinical trials with ^{64}Cu-SARTATE in NETs

Phase I CL01* trial

Phase II DISCO trial

Phase III registrational trial - in planning

- Based on the data from the DISCO and CL01 trials, a registrational Phase III study of ^{64}Cu-SARTATE in NETs is in planning.
- As a pivotal trial, its final results are intended to support an application to the US FDA for approval of ^{64}Cu-SARTATE as a new diagnostic imaging agent in NETs.



*Hicks R et al. First-in-human trial of ^{64}Cu-SARTATE PET imaging of patients with neuroendocrine tumours demonstrates high tumor uptake and retention, potentially allowing prospective dosimetry for peptide receptor radionuclide therapy. The Journal of Nuclear Medicine. 2019.

^{64}Cu-SARTATE: improved lesion detection and greater sensitivity vs. ^{68}Ga-DOTATATE

^{64}Cu-SARTATE vs. ^{68}Ga-DOTATATE*

~2x more foci
(441 vs. 228, respectively)

Higher sensitivity (discordant lesion-level)
(95.1% vs. 5.0%, respectively; P<0.001)

^{64}Cu-SARTATE

High foci-liver SUV ratio
(Foci mean SUVmax 44; Liver mean SUVmean 5; Mean ratio 11)*

Majority of adverse reactions were Grade 1 and self-limiting†

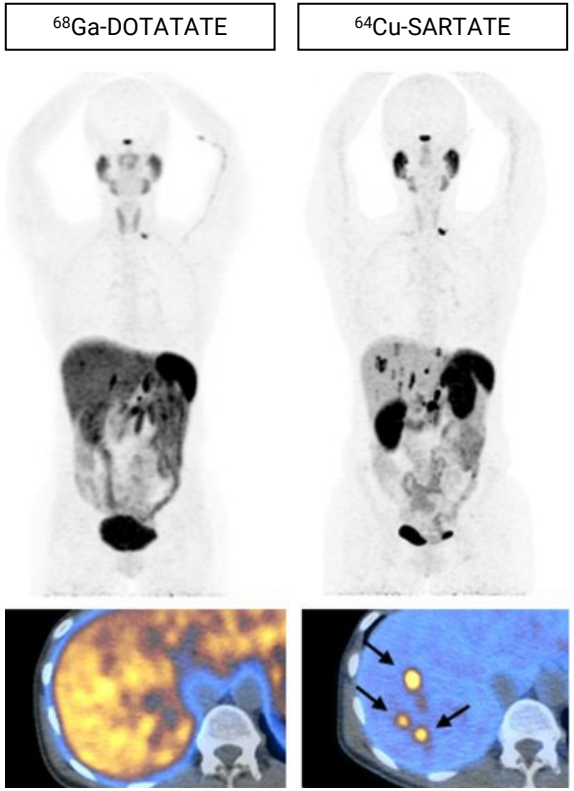
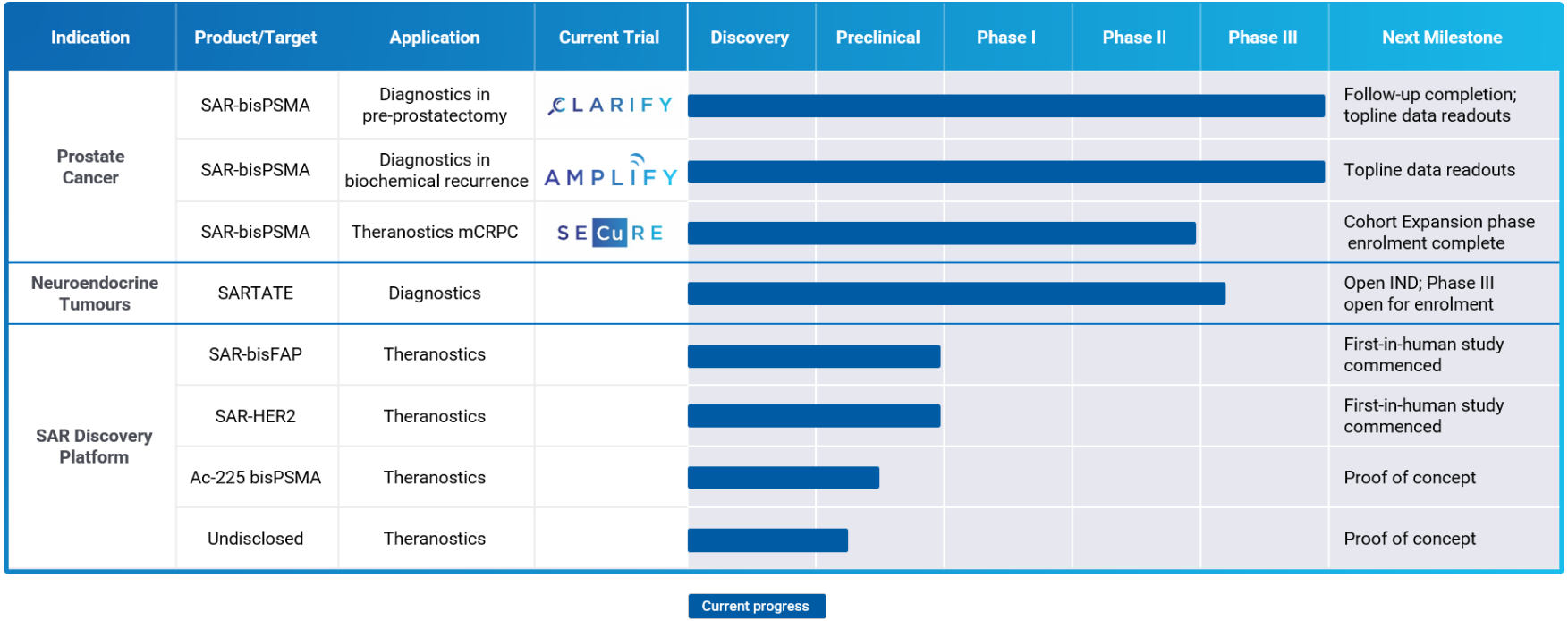


Image: representative case of one participant from the DISCO trial showing improved lesion detection and lower liver background with ^{64}Cu-SARTATE (same-day imaging) vs. ^{68}Ga-DOTATATE. PET: maximum intensity projections. Top images, PET; lower images, PET/CT fusion. Arrows show lesions clearly identified against low liver background with ^{64}Cu-SARTATE. *Lesion numbers & sensitivity expressed as the means across readers at 4 h ^{64}Cu-SARTATE imaging. Similar results were observed with 24 h ^{64}Cu-SARTATE. †Nine related treatment-emergent adverse events were observed in 7 participants (Grade 1: abnormal feces = 1; diarrhoea = 3; feces discolored = 1; nausea = 2; chest discomfort = 1; Grade 2: rash = 1). SUV: standardised uptake value. NCT04438304

Comprehensive pipeline from discovery to late-stage development

Clarity's products are progressing through various company-sponsored clinical trials in the US and Australia



CLARIFY and AMPLIFY are being conducted in the US and in Australia. SECuRE is being conducted in the US. SARTATE Phase III is planned to be conducted in the US.
Pipeline assets as of 25 November 2026. Data on file.

The year ahead: strong focus on NDA preparation and launch readiness

- **Topline results** for CLARIFY and AMPLIFY
- **High-impact scientific communications and exchange** (manuscripts, conference presentations and medical education)
- **Market shaping and account mapping** with a focus on developing disease state education and identifying high potential accounts
- **Preparation of NDA submission** with collective data across all studies
- **Supply-chain readiness** to ensure high throughput and sustainable supply from day one

Highly experienced team



Dr Alan Taylor
Executive Chairperson



Michelle Parker
CEO and MD



Michelle Hickey
Chief Technical Operations Officer



Eva Lengyelova
EVP – Clinical Development



Shaemus Gleason
Business Development



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 the radiopharmaceutical industry

- Decades of experience across science, nuclear medicine/PET and pharmaceutical industries
- Investment banking experience focused on the life sciences sector

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Thank you

