

Shareholder Briefing

Developing the next-generation of radiopharmaceuticals to improve treatment outcomes for children and adults with cancer

Dr Alan Taylor, Executive Chairperson

18 September 2024

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Who is Clarity

Our Team

 Our diverse team brings together many years of indepth expertise spanning corporate finance, management, operations, commercialisation and industry.

Our Shared Values

Innovation Thought leadership Collaboration

Reliability & trust Honesty & integrity Environment

Internal snapshot at 17 September 2024

Total employee count Growth from July 2023 58 employees

Gender diversity

41 to 58 employees

71% female

Geographic location

59% AUS 41% USA

Internal promotions FY23/24

Greater than 30%

Senior Executive Team

Dr Alan Taylor, PhD **Executive Chairperson**

Michelle Parker Chief Clinical Officer & **Executive Director**

Kathryn Williams Day VP, Regulatory Affairs & Quality

Eva Lengyelova VP, Clinical Development

Dr Othon Gervasio, DDS, MS, PhD

Chief Medical Officer

Dr Colin Biggin, PhD Chief Executive Officer & **Executive Director**

Dr Matt Harris, PhD, MBA Chief Scientific Officer

Shaemus Gleeson Executive VP, Operations

David Green Chief Financial Officer

Non-Executive Directors

Rosanne Robinson Non-Executive Director & Lead **Independent Director**

Dr Chris Roberts Non-Executive Director

Dr Thomas Ramdahl, PhD Non-Executive Director



Corporate Snapshot

Proprietary SAR Technology: a true platform technology

Three best-in-class products in clinical development and many in pre-clinical development protected by 29 patent families

Environmental advantages over current isotopes

No reliance on nuclear fuel cycle; TCTs do not generate long-lived waste products

Global leader in Targeted Copper Theranostics (TCTs)

Employs copper-64 for diagnosis and imaging and copper-67 for therapy offering high accuracy and precision for both diagnosing and treating disease

Targeted clinical development strategy

Commercialisation of diagnostic products first, generating revenue to fund late-stage therapeutic trials Significant supply, logistical, dependability and scalability benefits

Mass production of isotopes on cyclotrons and e-accelerators with finished products having an ideal product shelf life

Highly experienced leadership team

Diverse and in-depth expertise spanning corporate finance, operations, commercialisation & industry. Significant radiopharmaceutical experience across all functions



Clarity Pharmaceuticals is a clinical stage radiopharmaceutical company developing next-generation products to address the growing need for better diagnostics and treatments in oncology

ASX code:	CU6
Share Price ¹	A\$7.58
Cash at bank ²	A\$136.5M
Shares on issue ¹	315.8M
Options on issue ¹	25.2M
Market cap (undiluted) ¹	~A\$2.4B

- . As at 13 September 2024
- As at 30 June 2024

CU6: 12 month Share Price



ASX300 MSCI ASX200?

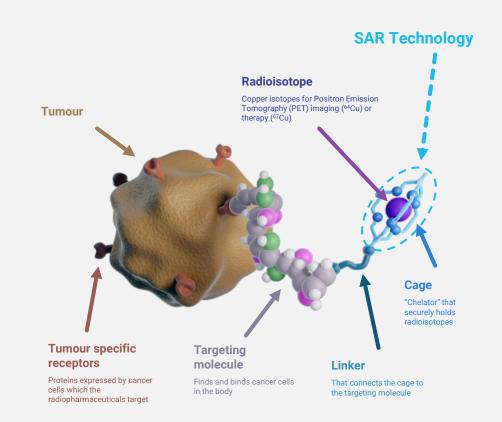


Clarity – The Copper Theranostics Company

Targeted Copper Theranostics are the nextgeneration disruptive platform in radiopharmaceuticals that employ the "perfect pairing" of copper-64 (⁶⁴Cu) and copper-67 (⁶⁷Cu) 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
 - TCTs 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



Why Copper?

The physical properties of copper-64 and copper-67 have optimal characteristics for global commercialisation

Diagnostic radionuclides

	Copper-64	Gallium-68	Fluorine-18
Half life	12.7 hours	1.1 hours	1.83 hours
Typical product shelf life	Up to 48 hours	Up to 4 hours	Up to 10 hours
Production	Cyclotron	Mainly from Generators	Cyclotron
lmaging window	From 1 to 48 hours	~60 mins	~60 mins
Ability to centrally manufacture	Yes	No	No

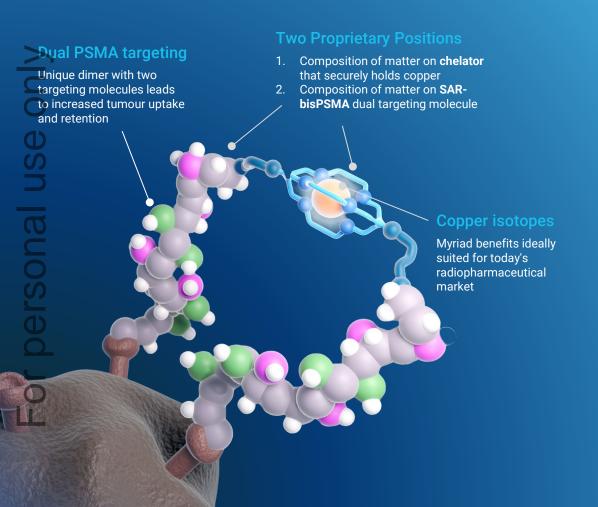




Therapeutic radionuclides

	Copper-67	Lutetium-177
Half life	2.6 days	6.7 days
Decay mode	Beta emitter	Beta emitter
Range in tissue	~0.2mm	~0.7 mm
Production mode	Electron accelerators	Nuclear reactors
Cost to scale supply	~US\$15M	>US\$1Bn
Time to scale supply	<18 months	~10 years





SAR-bisPSMA

What's all the hype?

Precision Targeting

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

Game changing treatment outcomes

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

Optimised dosing

⁶⁷Cu 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

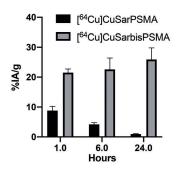
Monomer

- Pluvicto[®]
- Pylarify[®]
- 68Ga-PSMA-11
- ¹⁷⁷Lu-PNT2002

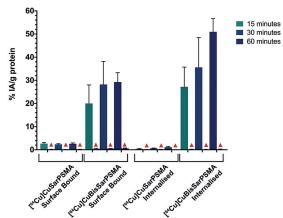


VS

Superior performance of bisPSMA compared to monomer PSMA



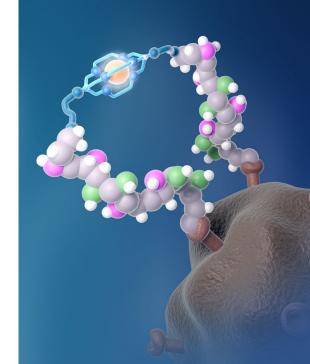
Significantly better binding and internalisation



Zia et al., 2019. Ang.Chem

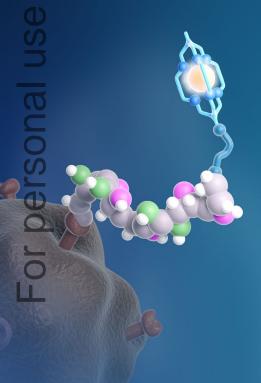
Dimer

SAR-bisPSMA



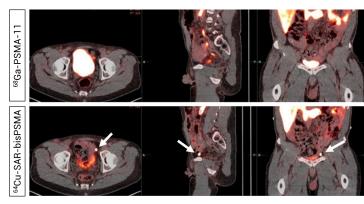
Monomer

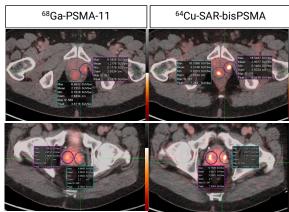
- Pluvicto[®]
- Pylarify[®]
- 68Ga-PSMA-11
- 177Lu-PNT2002



VS

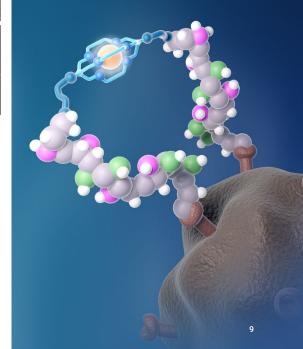
Superior performance of bisPSMA compared to monomer PSMA





Dimer

SAR-bisPSMA



SECuRE study design



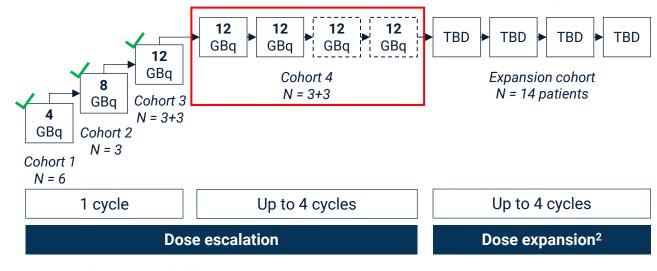
Phase I/IIa: safety and efficacy of ⁶⁷Cu-SAR-bisPSMA in metastatic castrate-resistant prostate cancer (mCRPC)

Key eligibility criteria

- Progressive mCRPC, prior ADT and at least one ARPI (pre- or post-chemotherapy)
- Positive ⁶⁴Cu-SAR-bisPSMA PET/CT scan (uptake [SUVmax] of at least 1 lesion higher than that of the liver)
- Patients with PSMA-negative lesions on MRI/CT are excluded

Maximum dose being investigated

12GBq (>50% higher than the approved dose of Pluvicto®)¹



Primary objectives include

- To investigate the safety and tolerability of ⁶⁴Cu/⁶⁷Cu-SAR-bisPSMA
- To investigate the anti-tumour efficacy of ⁶⁷Cu-SAR-bisPSMA (PSA and radiographic response)

No dose limiting toxicities have been observed in cohorts 1, 2, 3 and 4 to date. Recruitment is ongoing at sites in the United States.

^{2.} Dose level of the expansion cohort will be determined based on safety review from cohort 4 (TBD: to be determined). Dosimetry Phase not shown. Cohorts 1, 2 and 3 completed. Cohort 4 is currently recruiting (red box). Patients in cohort 4 will receive 2 doses of 67Cu-SAR-bisPSMA in cohort 4 if there is no radiographic progression. A Safety Review Committee meeting will take place after participants receive their 2 doses, with a period of 6 weeks for safety follow-up. Additional eligibility criteria apply NCT04868604.



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Pluvicto® FDA Approved Product Information. Information as of 15 March 2024.

Complete response following 2 cycles of ⁶⁷Cu-SAR-bisPSMA (8GBq)

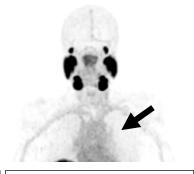
Multi-dose of ⁶⁷Cu-SAR-bisPSMA under Expanded Access Program (EAP)

- Complete anatomical response (CT; RECIST v1.1)
- Complete **molecular** response (PET)
 - Complete biochemical response (undetectable PSA)

64Cu-SAR-bisPSMA PET - MIP

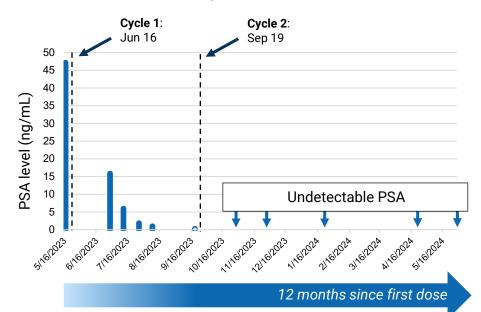






Post-cycle 2 of ⁶⁷Cu-SAR-bisPSMA

PSA reduction following 2 doses of ⁶⁷Cu-SAR-bisPSMA



Timeline

74-year-old male with Gleason 9 (5+4) metastatic castrate-resistant prostate cancer (diagnosed in 2017). Previous treatments included androgen deprivation therapy, docetaxel, abiraterone, enzalutamide and a clinical trial with a PARP inhibitor. Images show reduction in lesion uptake of ⁶⁴Cu-SAR-bisPSMA after two doses of ⁶⁷Cu-SAR-bisPSMA (no uptake post-2 cycles). Local RECIST assessment: complete response. No adverse events reported as related to ⁶⁴Cu-SAR-bisPSMA. Adverse events related to ⁶⁷Cu-SAR-bisPSMA: dry mouth, altered taste and thrombocytopenia (all Grade 1, improved), fatigue (Grade 2, resolved), anaemia (Grade 3, improved to Grade 2). Dash lines: administration of ⁶⁷Cu-SAR-bisPSMA. Timeline. "12 months": time since the first dose of ⁶⁷Cu-SAR-bisPSMA to most recent follow-up. EAP: Expanded Access Program. Data-cut off 19 April 2024. PSA Limit of detection: 0.05 ng/ml. Images: maximum intensity projection.

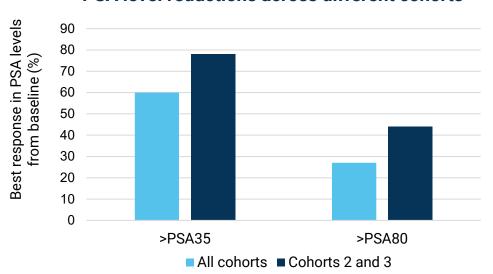


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67Cu-SAR-bisPSMA <u>single dose</u> leads to PSA reductions in heavily pre-treated mCRPC patients

PSA level reductions across different cohorts



78%

of patients showed reductions in PSA levels >35% (cohorts 2 and 3)

44%

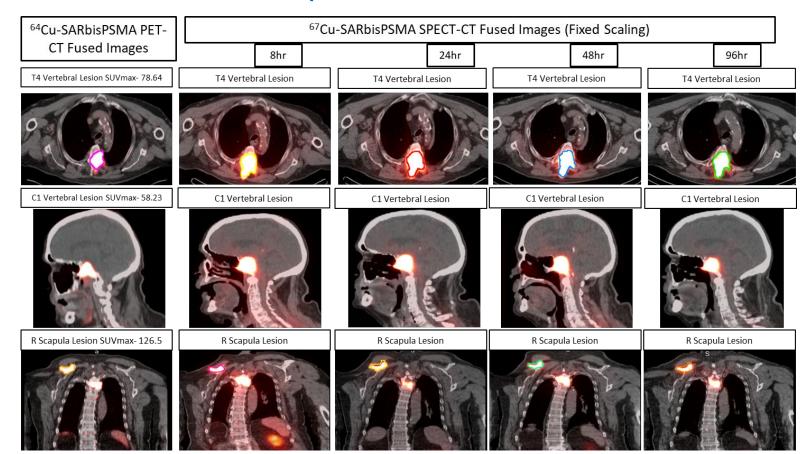
of patients showed reductions in PSA levels >80% (cohorts 2 and 3)

PSA reductions shown as the response observed post-single dose of ⁶⁷Cu-SAR-bisPSMA. PSA pre-dose value represents the most recent test result prior to the administration of ⁶⁷Cu-SAR-bisPSMA. At study entry, patients had median PSA of 117.1 ng/ml.



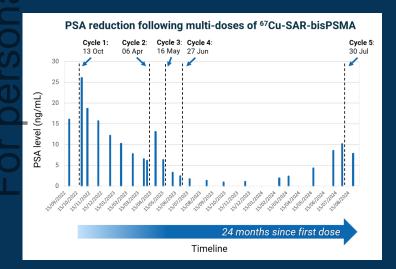
SECuRE cohort 1 - 4GBq dose level





US FDA Expanded Access Program

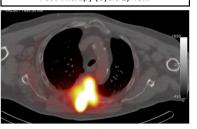
- Additional therapy cycles of ⁶⁷Cu-SAR-bisPSMA at the lowest 4GBq dose level have been requested under the US FDA EAP
- Early data indicates positive effects
- SPECT-CT images (on the right) demonstrate a reduction in the intensity of product uptake at the tumour sites after four doses, signalling tumour shrinkage
- Patient experienced a reduction in PSA levels >60% following the first dose, and a >90% decline in PSA after dose 4



4GBq of ⁶⁷Cu-SAR-bisPSMA over 4 cycles

⁶⁷Cu-SARbisPSMA SPECT-CT (Fixed Scaling)

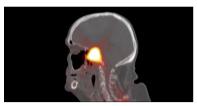
Post-Therapy (Cycle 1) 48hr



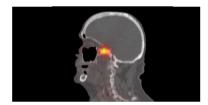
Post-Therapy (Cycle 4) 48hr

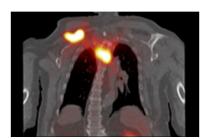


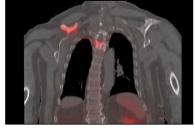
15 Oct 2022



29 Jun 2023







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⁶⁷Cu-SAR-bisPSMA (12GBq single dose) leads to >PSA and tumour volume reductions - Cohort 3



64Cu-SAR-bisPSMA PET - MIP Pre-67Cu-SAR-bisPSMA Post-67Cu-SAR-bisPSMA





PSA reduction achieved 8 weeks post-67Cu-SAR-bisPSMA

	Pre Tx	Post Tx	Δ (%)
PSA	270.9	20.8	-92.3
SUVmax	51.74	19.03	-63.22
Tumour Volume (ml)	1,040.92	635.44	-38.95

Participant from cohort 3 showing reduction in uptake of 64Cu-SAR-bisPSMA in prostate cancer lesions. Previous treatments: ADT, ARPI, chemotherapy and 2 investigational agents prior to enrolling in the SECuRE study. The participant received a single dose of ⁶⁷Cu-SAR-bisPSMA (12GBq). MIP: maximum intensity projection. Data on file. Data cutoff: 6 March 2024, NCT04868604.



or personal

or personal

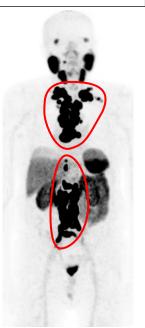
Two doses of 12GBq of ⁶⁷Cu-SAR-bisPSMA lead to >PSA and tumour volume reductions - Cohort 4



64Cu-SAR-bisPSMA PET

Pre-67Cu-SAR-bisPSMA

Post-cycle 2 of ⁶⁷Cu-SAR-bisPSMA







	Pre Tx	Post Tx	Δ (%)
PSA	157.4	12.1	-92.3
SUVmax	80.0	71.2	-9.1
Tumour Volume (ml)	868.2	342.5	-60.6

mCRPC participant from cohort 4 showing reduction in uptake of ⁶⁴Cu-SAR-bisPSMA, following 2 cycles of 12GBq ⁶⁷Cu-SAR-bisPSMA (extensive metastasis of prostate cancer to the lymph nodes, regions highlighted by the red lines). Previous treatments: ADT, ARPI and an investigational agent prior to enrolling in the SECuRE study. Post-cycle 2 scan (64Cu-SAR-bisPSMA) performed approximately 8 weeks after the second dose of 67Cu-SAR-bisPSMA. Data cut-off: 7 September 2024. MIP: maximum intensity projection. NCT04868604.



⁶⁷Cu-SAR-bisPSMA has a**>**favourable safety profile

Cohorts 1-3 Adverse event (AE)	Grade 3 N = 15 (100%)
Any drug-related AEs	3 (20)
Occurring in at least 1 participant	
Anaemia	2 (13)
Thrombocytopenia	1 (7)
Leukopenia	1 (7)
Lymphopenia	1 (7)

Demographics summary: all participants had mCRPC at study entry. Median number of lines of therapy prior to receiving ⁶⁷Cu-SAR-bisPSMA: 4 (range 2-6). Previous treatments included ADT, ARPI, investigational agents, chemotherapy (67%, 10/15) and other radioligand therapies. Median PSA at study entry: 117.1 ng/ml (range 0.11-1,494.2).



Cohorts 1-3 (single dose): most adverse events (AEs) were lower Grade, with only 3/15 patients developing Grade 3 AEs (no Grade 4/5)

- No AEs were related to ⁶⁴Cu-SAR-bisPSMA
- AEs were reported as related to ⁶⁷Cu-SARbisPSMA in 8 out of the 15 trial participants (all Grades)
- Most AEs related to ⁶⁷Cu-SAR-bisPSMA were Grade 1 or 2
- No Grade 4 or 5 AEs were reported in the study

Cohort 4 (multi-dose): almost all AEs were mild or moderate (majority either resolved or improved at the last assessment). No DLTs observed.

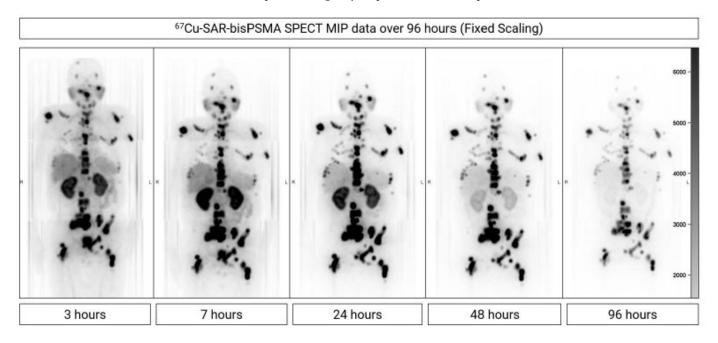


personal use

Dosimetry and clearance



Serial SPECT imaging after administration of therapy showed prolonged tumour retention of 67Cu-SAR-bisPSMA with non-tumour bound activity clearing rapidly via the kidneys.



Dosimetry assessment in a participant from cohort 3 (12GBq). SPECT was performed at different timepoints (3, 7, 24, 48, and 96 hours post-injection of ⁶⁷Cu-SAR-bisPSMA). Images show fast clearance from the kidneys, compared to prolonged retention of ⁶⁷Cu-SAR-bisPSMA in lesions.



Next-generation SAR-bisPSMA diagnostic is coming

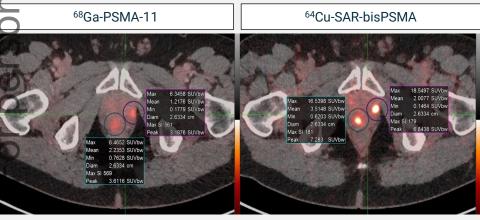
Improved uptake of SAR-bisPSMA may support better diagnosis compared to first-generation PSMA PET agents. Significant market opportunity to displace currently approved products, which generated >US\$1.1Bn in 2023

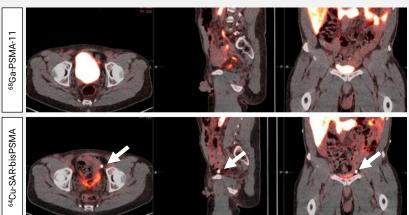
Lantheus: PYLARIFY® (18F-DCFPyL) US sales Q2 24: ~US\$273M Specificity - High Telix: Illuccix ® (generic PSMA-11 kit) US sales Q2 24: ~ US\$121M Sensitivity - Low

⁶⁴Cu-SAR-bisPSMA vs. ⁶⁸Ga-PSMA-11 – PROPELLER study (pre-prostatectomy)

2-3x more uptake and contrast

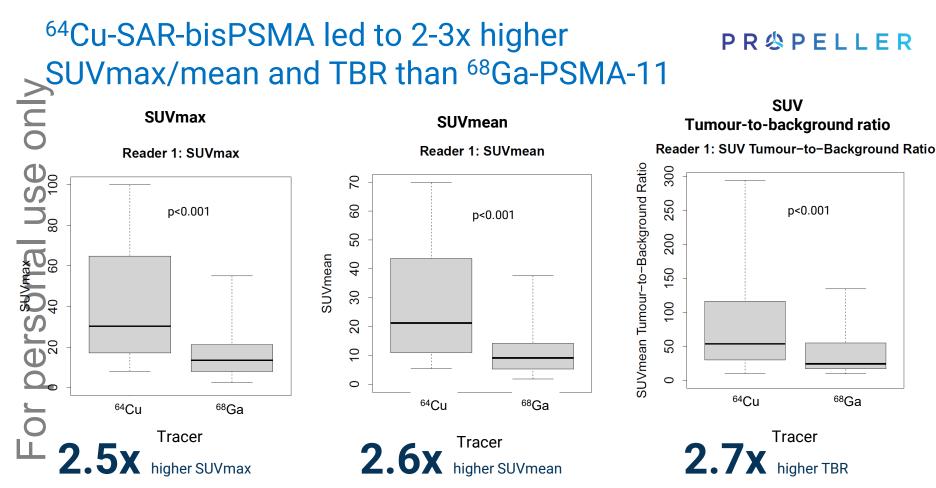
More lesions identified







PR & **PELLER**





Copper brings significant additional advantages 🛛 📽 C O B R A



Beyond the supply chain advantages of a 12.7-hour half-life PET imaging agent, SAR-bisPSMA allows patients to be Imaged from 1 hour to >24 hours post administration.

⁶⁴Cu-SAR-bisPSMA enhanced performance could lead to considerable impact on treatment decisions and outcomes

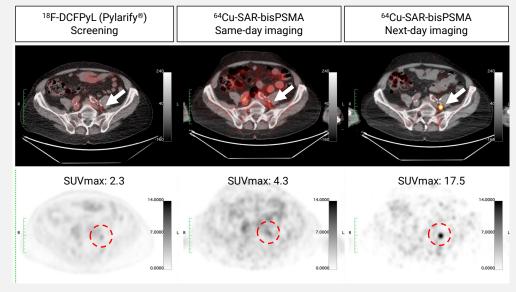
Patients with negative/equivocal SOC scans - COBRA study (biochemical recurrence)

82% more lesions detected on

next-day imaging (2 mm-range)

64Cu-SAR-bisPSMA Same-day imaging Next-day imaging or pers

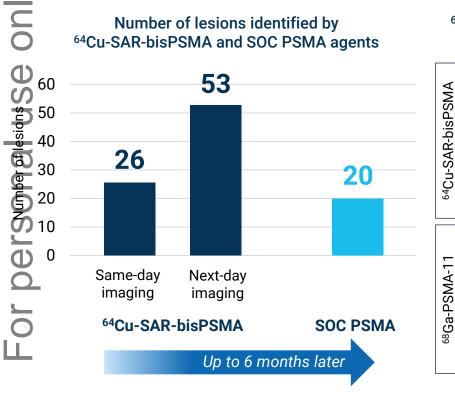
34% more patients with a positive scan on next-day imaging



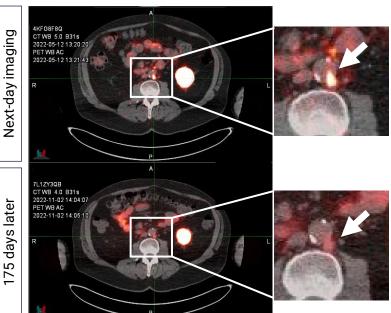


⁶⁴Cu-SAR-bisPSMA identifies lesions months before currently approved PSMA PET agents





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



No lymph node involvement was detected

Prostate cancer in lymph node confirmed via

histopathology

Higher uptake and contrast in lesions on next-day © COBRA imaging and detection of lesions in the 2-millimeter range

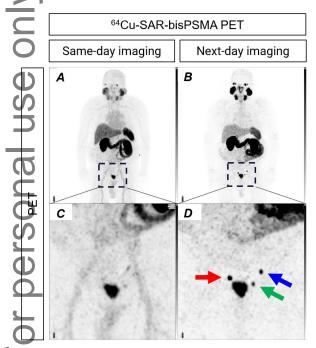
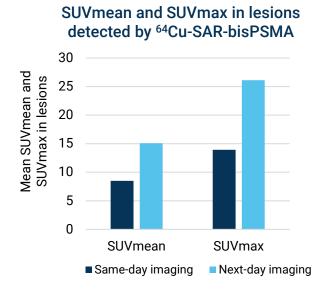
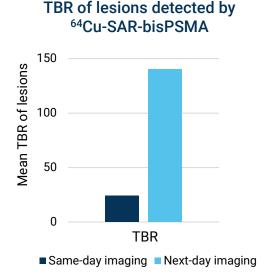


Figure 1. Pelvic lymph nodes showing uptake of ⁶⁴Cu-SAR-bisPSMA on next-day imaging (arrows, B and D). Blue arrow: lesion size 3.8 mm x 4.4 mm, SUVmean 20.6, SUVmax 22.1 and TBR 130.1. Green arrow: lesion size also 3.8 mm x 4.4 mm, SUVmean 11.9, SUVmax 12.8 and TBR 75.3. Red arrow: size >5 mm. Inset 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 ⁶⁴Cu-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 cluteus region.

Clinical development in multiple cancers

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

Clinical development pipeline as of 30 August 2024

Indication	Product	Application	Current Trial	Discovery	Preclinical	Phase I	Phase 2	Phase 3
	SAR-bisPSMA	Theranostic mCRPC	SECURE		=		*	
	SAR-bisPSMA	Diagnostic in pre- radical prostatectomy	CLARIFY			ÄK:		
Prostate Cancer	SAR-bisPSMA	Diagnostic in BCR PCa	♥ COBRA					***************************************
	SAR-BBN	Diagnostic in BCR PCa	SABRE					
	SAR-BBN	Theranostic mCRPC	C 🔊 M B A T		***			
Neuroblastoma	SARTATE	Theranostic	CL04		=			
NETs	SARTATE	Diagnostic	DISC		7	Š :		
	Ac-bisPSMA	Theranostic		*				
SAR Discovery	TCT and I/O combination	Theranostic		*==				
Platform	Pan-cancer TCT	Theranostic		*==				
	Multiple novel TCTs	Theranostic		₩				

Current progress

12 month progress

Note clinical development pipeline is indicative only, subject to review.

All US studies are conducted under Investigational New Drug Applications



or personal use

Robust IP driving the Discovery program

Clarity's proprietary SAR Technology platform can be used in conjunction with any number of targeting ligands to create new products and new IP

Broad Patent Portfolio

Platform Protection

Granted and new chelator patents used in further developing lead and back-up products

Product Protection

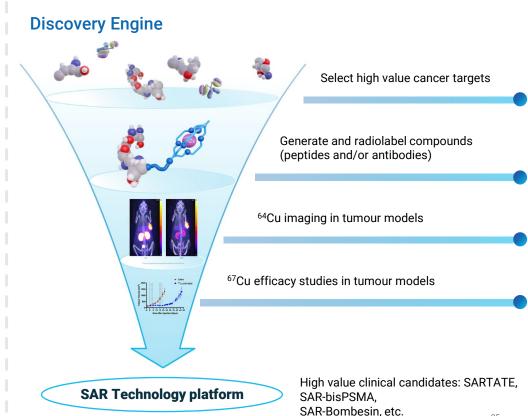
- Maintenance of pending applications for potential continuation or divisional filings on existing important patents
- New patents filed on lead and back-up compounds

Pipeline Protection

- New chelator patents used in future discovery products
- New patents filed on novel treatment regimes for radiopharmaceutical applications

Manufacturing & Process Protection

- Manufacturing and formulation patents
- New patents filed on manufacturing processes

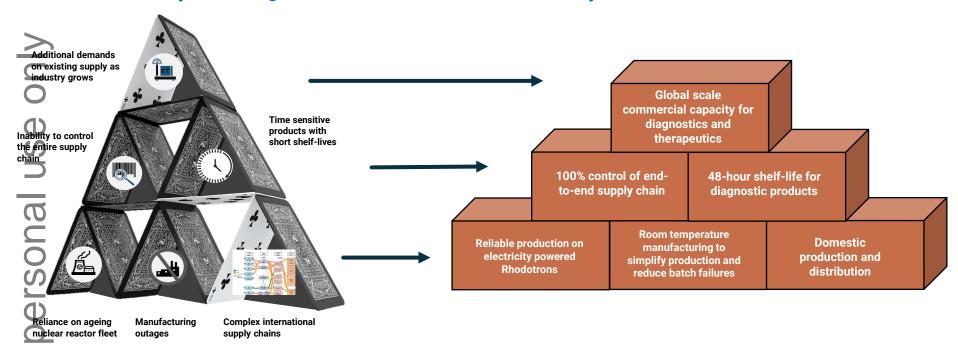


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Current industry challenges with ⁶⁸Ga & ¹⁷⁷Lu

Clarity's TCT Solution with 64Cu & 67Cu





Novartis halts US production of cancer radiotherapies, citing potential quality issues

By Angus Liu • May 5, 2022 12:44pm

"We have patients on months long waiting lists when this may be all the time they have, and so it's been really disheartening to have to deal with these things"

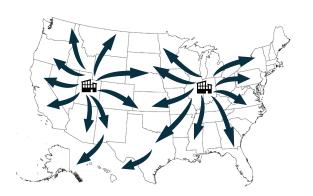
- Roby Thomas, MD, a medical oncologist and hematologist at UPMC Hillman Cancer Center



Next-generation theranostics provide solutions to the challenges with current-generation radiopharmaceuticals

Opportunities with 64Cu (half-life = 12.7h)

- Can be mass produced on cyclotrons with solid targetry
- Every US zip code covered from 1 location
- Patient flexibility with product shelf life of up to 48 hours
- Operational flexibility with imaging timepoints up to 72 hours
- 9-22 times lower exposure than commonly used ¹⁸F products
- Ability to centralise investments and supply the country
- Delivered as a ready-to-use cGMP product



Opportunities with Rhodotron produced ⁶⁷Cu

- Commercially available high powered rhodotron with a small footprint (10' diameter and 11' tall)
- Scalable with relatively small investments
- Purpose-built supply in the markets of focus, including a US domestic supply



- · Only inputs are electricity and Zinc
- · No long-lived impurities
- Exclusive supply agreement with NorthStar Medical Isotopes
- A single rhodotron can produce commercial quantities of ⁶⁷Cu

"Access to reactors will soon become the bottleneck for 177Lu"1



Strong strategic interest in radiopharmaceutical assets

-	Date	Target	Acquirer	Acquisition value	Main asset
)	May 24	Mariana Oncology	Novartis (NYSE: NVS)	Up to US\$1.75bn ¹	Preclinical stage assets, led by ²²⁵ Ac-MC-339
5	Mar 24	Fusion Pharmaceuticals	AstraZeneca plc (LON:AZN)	US\$2.4bn ¹	²²⁵ Ac-PSMA I&T for mCRPC
5	Dec 23	RayzeBio, Inc.	Bristol-Myers Squibb Company (NYSE:BMY)	US\$4.1bn	²²⁵ Ac-DOTATATE
) -))	Oct 23	POINT Biopharma Global Inc.	Eli Lilly (NYSE:LLY)	US\$1.4bn	Early Phase FAP product & production Facility. Main clinical assets already licensed to Lantheus in 2022

Note: 1. Including upfront cash portion and maximum potential contingent value payments

"The willingness of large pharma companies to pay high premiums for radiopharmaceutical companies further demonstrates the burgeoning interest in the field"

- Nature, March 2024

Clarity's copper platform, strong prostate pipeline and therapeutic and diagnostic efficacy data represents an attractive opportunity to grow a significant radiopharmaceutical franchise in oncology and other indications

- Four major deals in the global radiopharmaceuticals sector over the last 8 months highlights the strong strategic interest in radiopharmaceuticals
- Extremely limited number of clinically advanced radiopharmaceutical companies remaining globally which would provide pharmaceutical companies with a platform entry point to radiopharmaceutical therapeutics
- Clarity's TCT platform, potential best-in-class assets in large indications, strong IP position, and significant supply chain advantages differentiate Clarity in the market
- Exciting efficacy and safety data in therapies and diagnostics has attracted interest from a range of pharmaceutical companies
- A strong Balance Sheet allows Clarity to fully exploit its platform, products and positioning to maximise shareholder value



Summary

Global leader in Targeted Copper Theranostics (TCTs)

- Exciting efficacy and safety data to date with therapy and imaging
- Extensive pipeline of TCTs based on ⁶⁴Cu for diagnosis and ⁶⁷Cu for therapy
- Multiple therapeutic and diagnostic trials in progress, including a Phase III registrational trial
- TCTs address the current manufacturing and logistical limitations in the growth of radiopharmaceuticals
- TCTs are scalable, sustainable and dependable
- Broad and defensible IP portfolio of patent families across the SAR Technology platform, pipeline and products
- Pipeline includes large and orphan indications, with focus on the US for first approvals
- Led by an experienced management team and Board with significant years of active involvement in the radiopharmaceutical industry
- Highly active M&A sector with numerous recent acquisitions





Thank you

Contact details

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