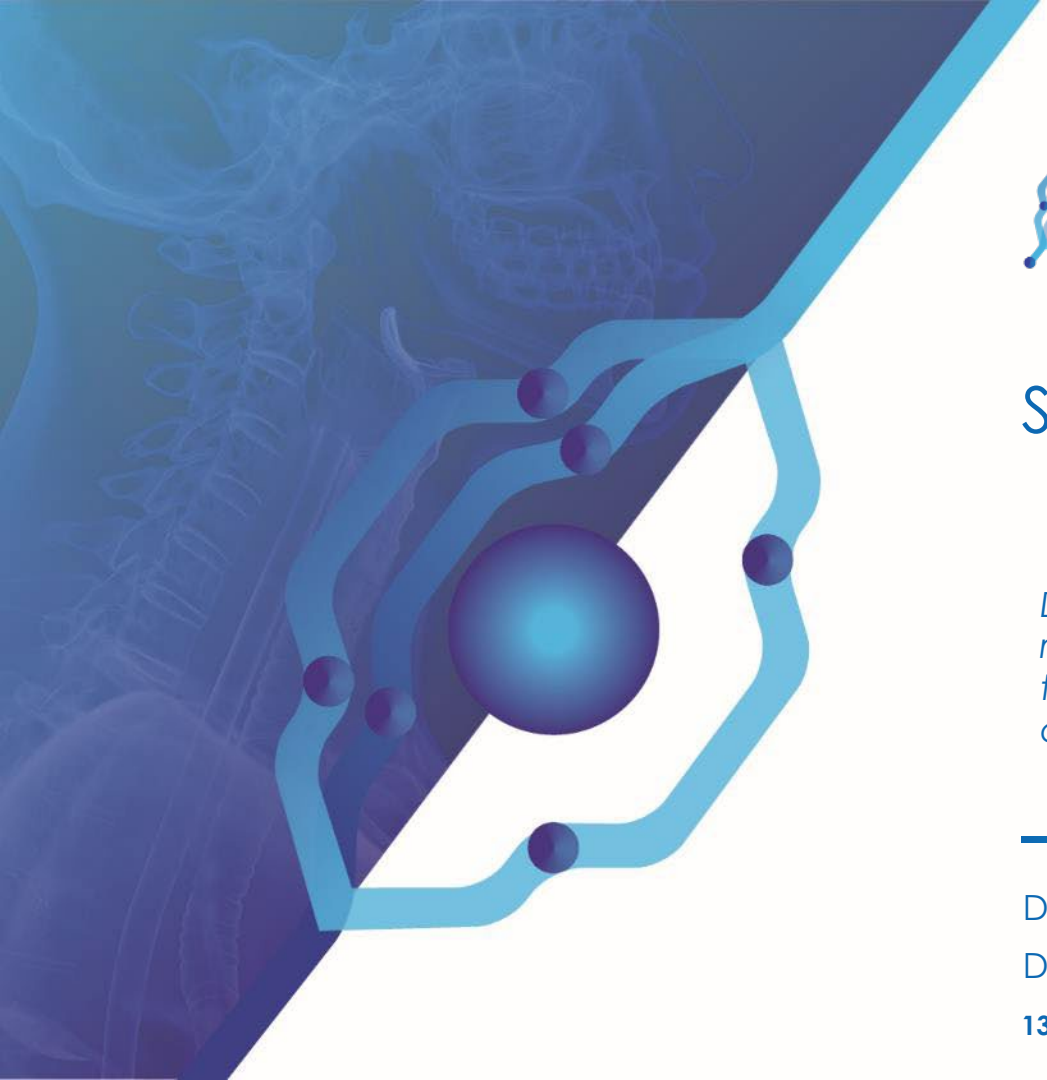

CLARITY PHARMACEUTICALS

Shareholder Update

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

Dr Alan Taylor, Executive Chairperson

Dr Colin Biggin, Chief Executive Officer

13 March 2023

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Clarity in a nutshell (ASX:CU6)

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

Proprietary SAR Technology: a true platform technology

Three best-in-class products in clinical development offering high accuracy and precision for both diagnosing and treating disease

Global leader in Targeted Copper Theranostics (TCTs)

Employs copper-64 for diagnosis and imaging and copper-67 for therapy

Significant supply, logistical, dependability and scalability benefits

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

Environmental advantages over current isotopes

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

Targeted clinical development strategy

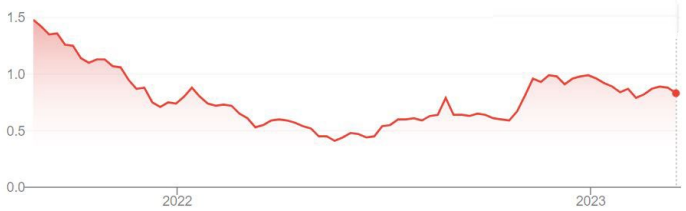
Diagnostic products will be the first to reach the market, generating revenue to fund late-stage therapeutic trials

Highly experienced leadership team

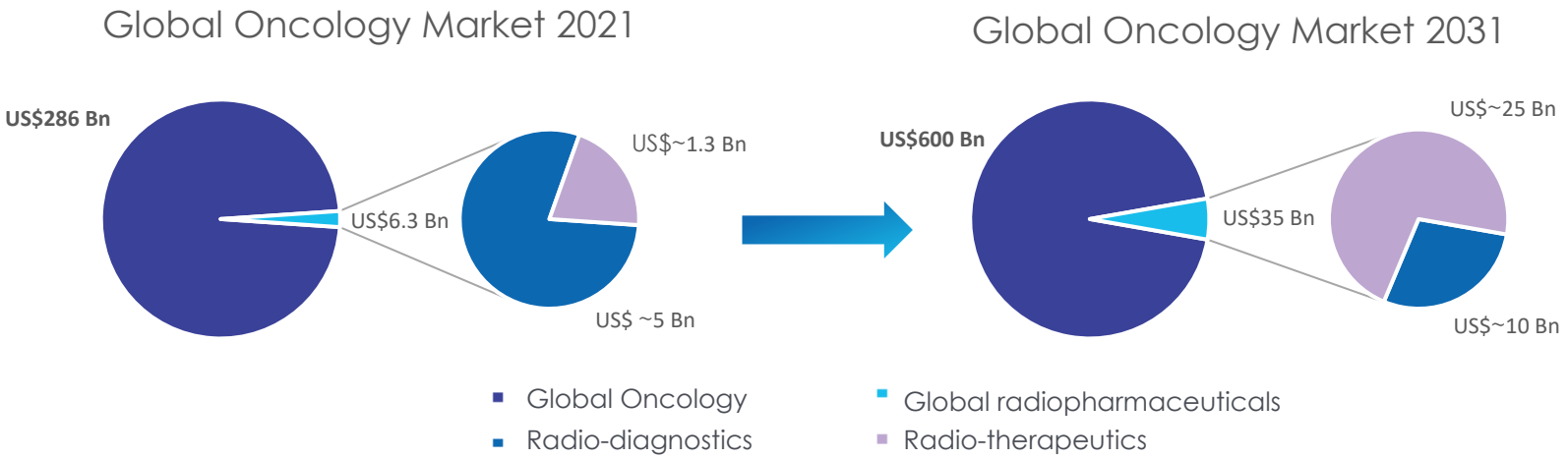
Diverse and in-depth expertise spanning corporate finance, operations, commercialisation & industry

ASX Code: CU6

- Share Price: **$0.88** as at 10 Mar 2023
- Cash at bank: **$75.9M** as at 31 Dec 2022
- R&D tax incentive for FY22: **~$6.7M**
- **~$83M** to fund the existing trials and provide cash runway into 2024
- Shares on issue: 260.3M
- Options on issue: 25.1M
- Market capitalisation: **$229M** (undiluted) as at 10 Mar 2023



Radiopharmaceuticals: Market overview



	2021		2031
Global oncology market	US$ 286 Billion	→	US$ >600 Billion
Global radiopharmaceuticals	US$ 6.3 Billion	→	US$ 35 Billion
Radio-diagnostics	US$ ~5 Billion	→	US$ ~10 Billion
Radio-therapeutics	US$ ~1.3 Billion	→	US$ ~25 Billion

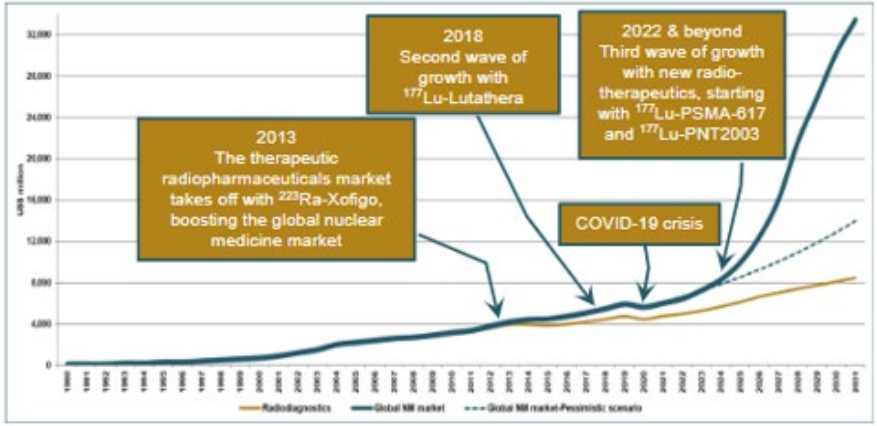
Growth drivers

Radiopharmaceuticals have shown significant growth potential both diagnostically and therapeutically and companies similar to Clarity have proven to be very profitable

Positive changes have driven Big Pharma interest in the space

- Re-imbursement
- Pricing (Pluvicto >US$ 250k for 6 doses)
- Broader clinician uptake
- Positive Phase III results for Pluvicto

The Nuclear Medicine Market 1990-2031



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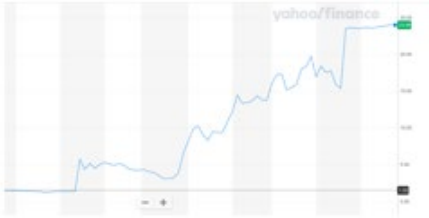
ENDOCYTE



Advanced Accelerator Applications

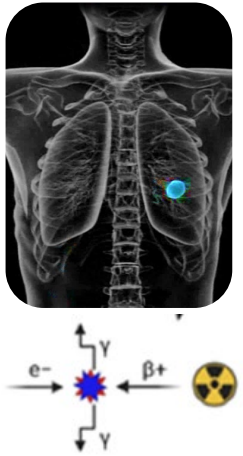
Targeted radiopharmaceuticals are becoming a new pillar of oncology

Radiopharmaceuticals are systemic agents that can be used to diagnose and treat different types of cancer

Targeted radiopharmaceuticals use special targeting agents which go to specific receptors on specific cancers. Delivering radiation to the cancer and minimising the off-target effects.

PET diagnostics

- Use positron emitting radionuclides to visualise the location of cancers in the body via PET imaging
- Provides information to clinicians on a broad range of areas including identifying disease, monitoring progression and response to therapy



PET Imaging

Therapy

Beta therapeutics

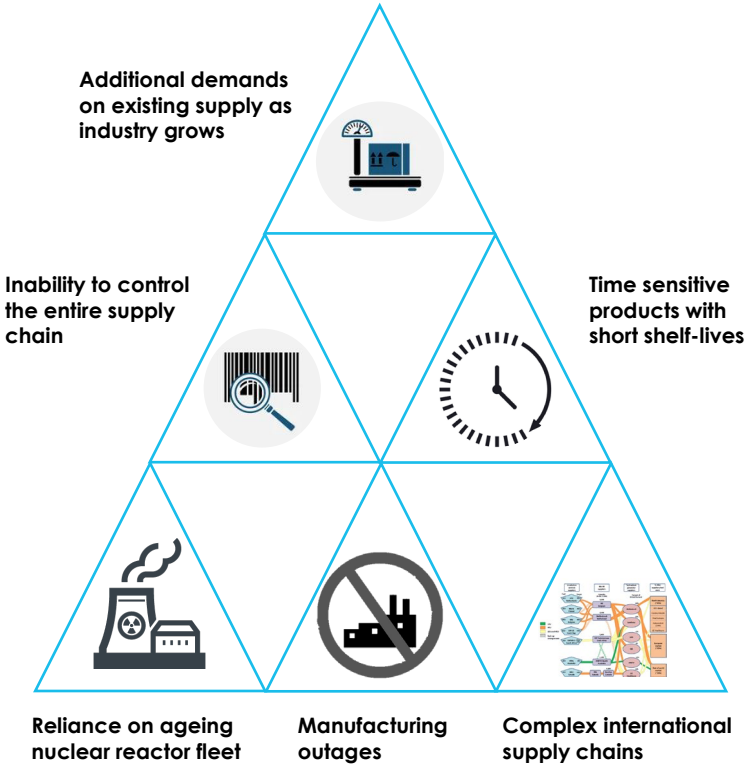
- Use powerful beta emitting radionuclides to damage/kill the cancer cells
- Where therapy is guided by a diagnostic radiopharmaceutical, the term "theranostics" can be used

Recent approved diagnostics:
Pylarify: Q4 22 US sales ~USD160.6M

Recent approved therapy:
Pluvicto: Q4* 22 US sales USD179M

*2nd full quarter of product launch

Current industry challenges



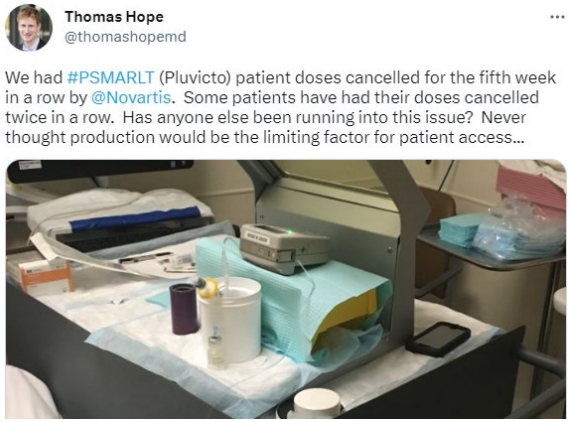
Combined with a history of supply issues

Creates challenges for prescribers

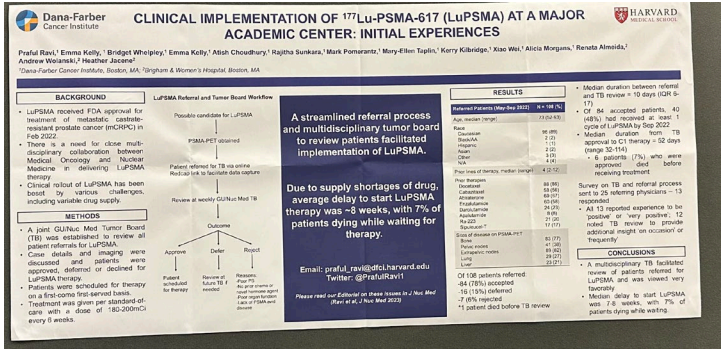
Work to be done to convince oncologists that there is a safe, dependable and reliable source of radiopharmaceutical products.

Without this supply chain, radiopharma may struggle to become a pillar of oncology when its competing with long shelf life oral oncolytics.

Current industry challenges

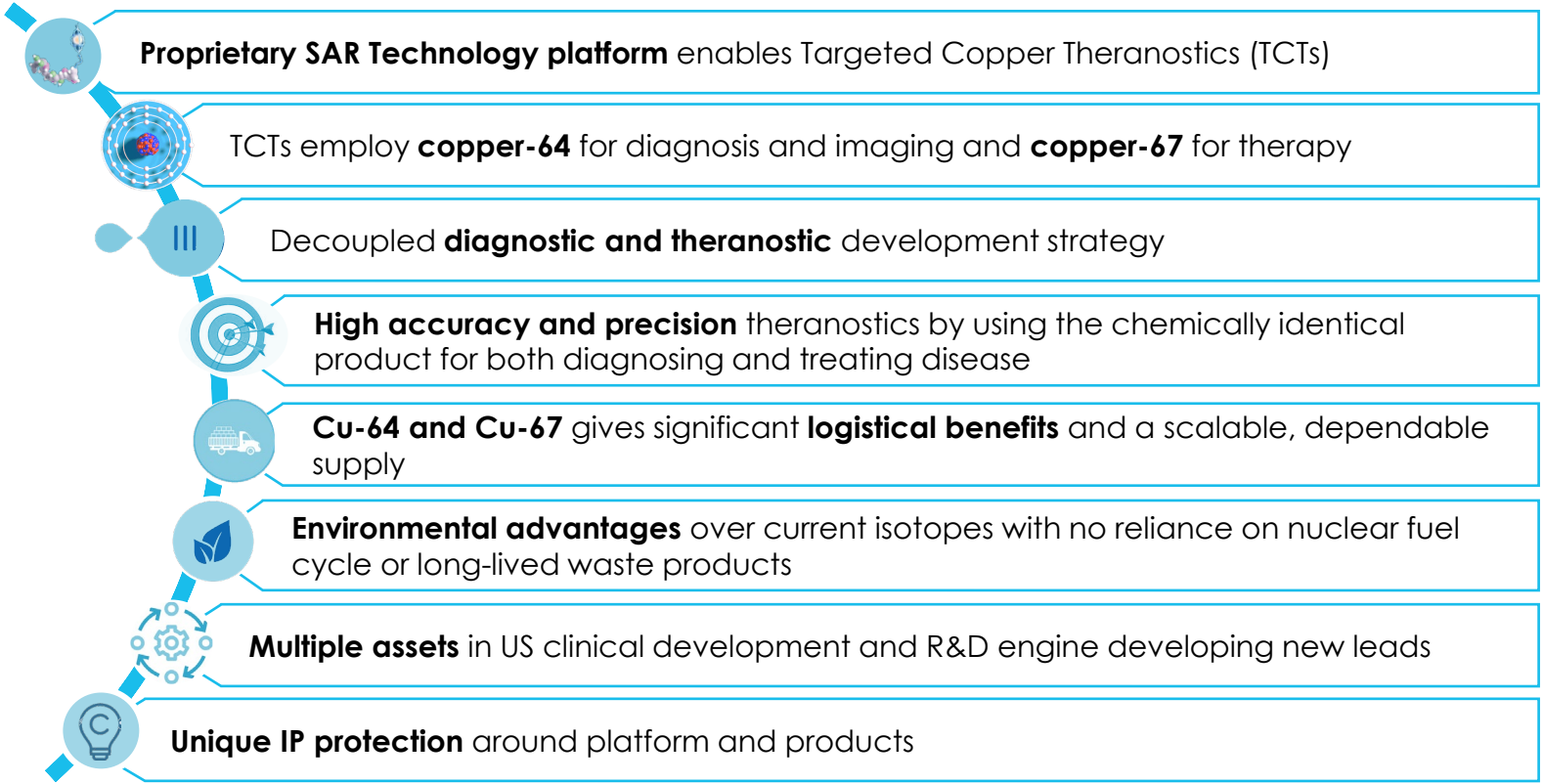


ASCO Genitourinary Cancers Symposium



Clarity's TCTs address the current industry challenges

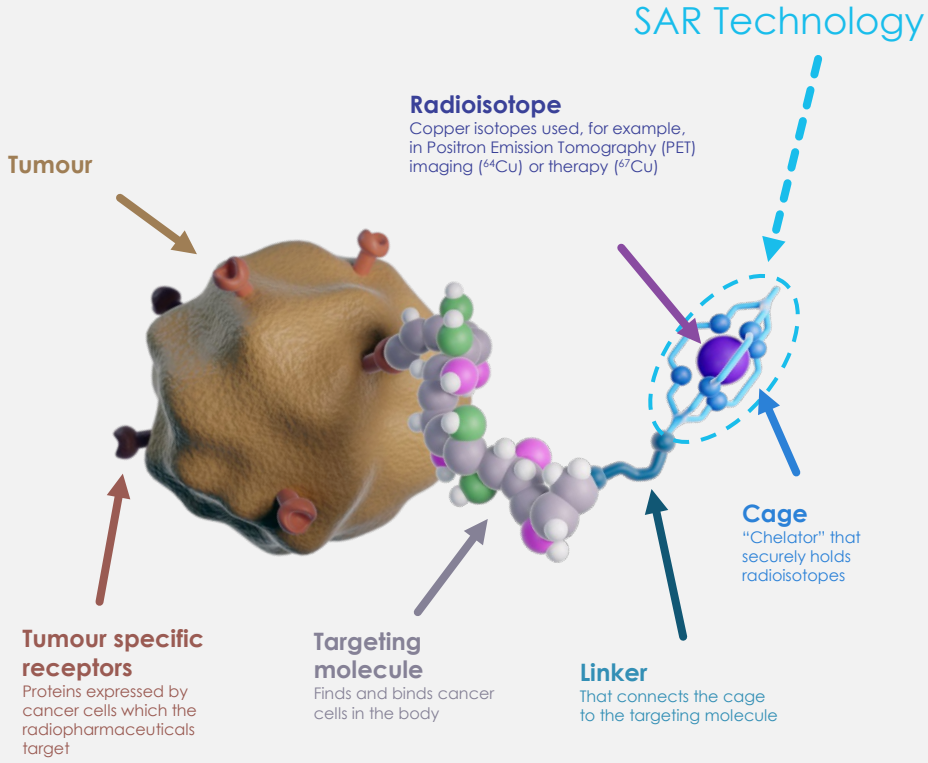
Clarity Pharmaceuticals is a clinical stage radiopharmaceutical company with a mission to develop next-generation products that improve treatment outcomes for children and adults with cancer



Proprietary SAR Technology platform

Theranostic radiopharmaceuticals have four main elements: a radioisotope, cage, linker and targeting ligand and are administered intravenously

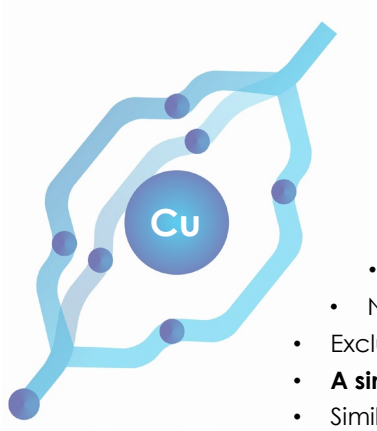
- SAR Technology is a proprietary, highly specific and highly stable bifunctional cage (chelator) with a superior ability to retain copper isotopes within it and prevent their leakage into the body.
- Unlike the current generation of radiopharmaceuticals, SAR products do not require heating in order to bind copper to the cage.



TCTs: A robust foundation for future growth

Copper-64 (half-life = 12.7 hours)

- Mass produced on cyclotrons
- Every US zip code covered from 1 location
- Patient flexibility with product shelf-life of up to 48 hours
- Operational flexibility with imaging timepoints from 1 to 72 hours
- Delivered as a ready-to-use cGMP product
- 9-22 times lower exposure than commonly used ^{18}F products
- The ability to centralise capital investments and supply entire continents
- Similar half-life to iodine-123 which is routinely produced centrally



Copper-67 (half-life = 2.6 days)

- Optimal half-life for peptide-based therapy
- Commercially available high powered rhodotron for mass production with a small footprint
- 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 ^{67}Cu**
- Similar half-life to yttrium-90, used in SIR-spheres.

Clarity's solution to radiopharmaceutical supply threats

- No time sensitive international supply chains
- No local production requirements (reduced costs and patient safety risk; universal availability)
- Economies of scale from the same manufacturing process
- Ability to quickly integrate new products

The environmental considerations*

- As the number of patient treatments increases, environmental factors will impact the selection of theranostic radiopharmaceuticals
- Production of ^{64}Cu and ^{67}Cu has favorable environmental characteristics, significantly reducing the environmental impact compared to the current generation theranostics based on ^{68}Ga or ^{177}Lu
- This is highly relevant considering the forecasted growth of theranostics over the next decade

*Norenberg J et al. Environmental Considerations Resulting from the Increased Use of Theranostics: Advantages of Targeted Copper Theranostics. Journal of Nuclear Medicine June 2022, 63 (supplement 2) 2655.19. https://jnm.snmjournals.org/ content/63/supplement_2/2655

Dual development strategy

SAR Technology enables a synergistic development of stand-alone diagnostics as well as paired theranostics

Diagnostics based on ^{64}Cu

- Broad market opportunities
- Address the current supply and logistical constraints on the industry
- Provide universal access to diagnostic agents
- Short time to market, provides revenue for later stage therapy development
- Low production and distribution costs shield potential revenues from lost of pass-through-status after 3 years in the US

Dx revenue pays for late-stage Tx clinical development

Marketed Dx re-enforces Tx position

Theranostics based on ^{64}Cu/^{67}Cu

- High precision, high accuracy
- Blockbuster potential for a range of assets
- Easy to scale up
- Domestic US supply
- No reliance on aging nuclear reactors

Diagnostic imaging scan with copper-64

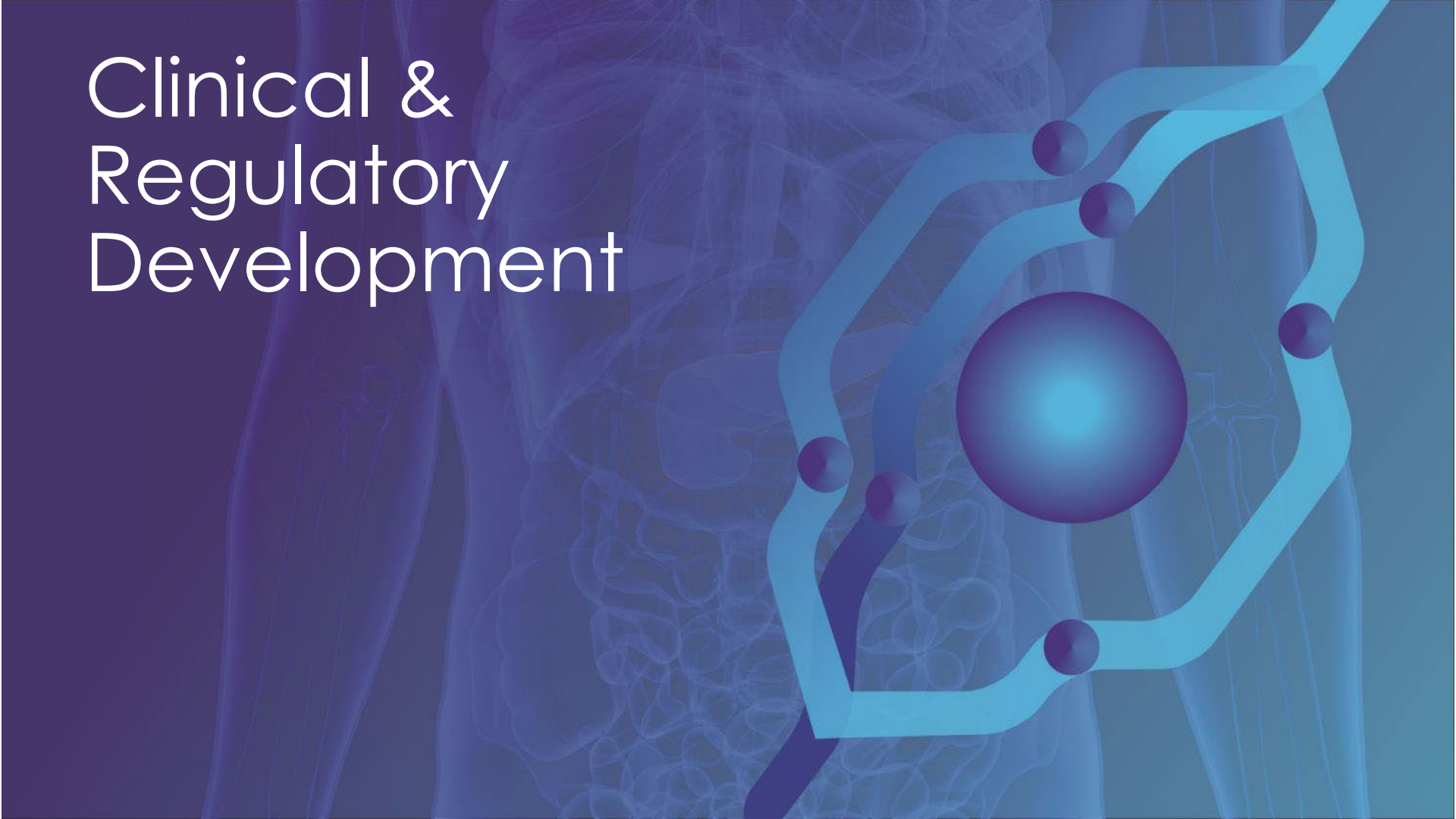
Positive for target

Copper-67 therapy

Negative for target

Conventional therapy

Clinical & Regulatory Development



Three core product areas in clinical trials

Clarity has an active clinical development program in multiple oncology indications with unmet needs through a range of products and their applications. The SAR platform is also used in our SAR-DISCOVERY program which has significant synergies with the existing clinical program.

Product	SAR-bisPSMA Cancers that express Prostate Specific Membrane Antigen (PSMA)	SAR-Bombesin Cancers that express Gastrin Releasing Peptide receptor (GRPr)			SARTATE™ Cancers that express Somatostatin Receptor 2 (SSTR2)	DISCOVERY Developing new products based on Cu-64/Cu-67
Indication	Prostate Cancer			Breast Cancer	Neuro-blastoma	NETs
Current trials	Theranostic	Diagnostic	Theranostic	Diagnostic	Diagnostic	Theranostic	Diagnostic
Trial name/phase	SECURE Phase I/IIa	COBRA Phase I/II PROPELLER Phase I	COMBAT Phase I/IIa	SABRE Phase II BOP Phase II IIT	C-BOBCAT Phase I IIT	CL04 Phase I/IIa	DISC Phase II

Clinical development in multiple cancers

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

Clinical development pipeline as of 13 March 2023

Indication	Product	Application	Current Trial	Discovery	Preclinical	Phase I	Phase 2	Phase 3	Next Milestone
Prostate Cancer	SAR-bisPSMA	Theranostic mCRPC	SECuRE						SECuRE cohort 1 recruited
	SAR-bisPSMA	Diagnostic in pre-radical prostatectomy	PROPELLER						Phase III protocol agreed
	SAR-bisPSMA	Diagnostic in BCR PCa	COBRA						COBRA top line data
	SAR-BBN	Diagnostic in BCR PCa	SABRE						SABRE 50% recruitment
	SAR-BBN	Theranostic	COMBAT						Recruitment commences
Neuroblastoma	SARTATETM	Theranostic	CL04						CL04 cohort 3 completed
NETs	SARTATE™	Diagnostic	DISCO						DISCO recruitment complete
SAR Discovery Platform	Undisclosed	Undisclosed							
	Undisclosed	Undisclosed							

Current progress | 12 month progress

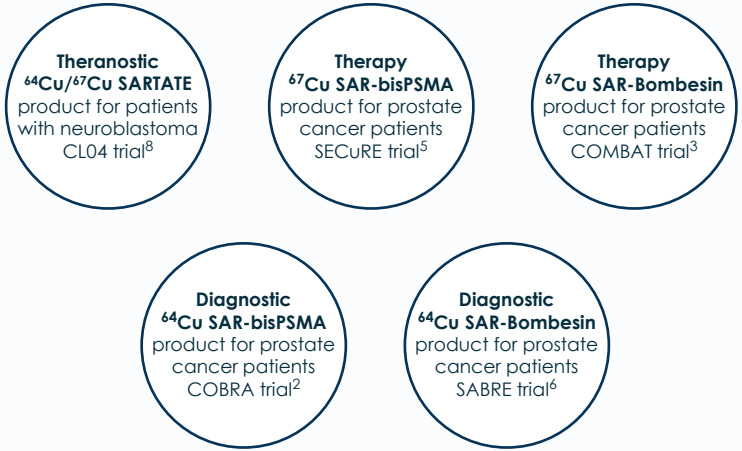
Note clinical development pipeline is indicative only, subject to review.

All US studies are conducted under IND

Regulatory Overview

Strong focus on the US FDA and first approvals in the US

All six clinical-stage products under IND in the US



Two Orphan Drug Designations and two Rare Paediatric Disease Designations

Rare Paediatric Disease Designation

US FDA Rare Paediatric Disease Designation (RPDD) for:
- ^{67}Cu SARTATE granted (neuroblastoma therapy)
- ^{67}Cu SARTATE granted (management of neuroblastoma)

Orphan Drug Designation

US FDA Orphan Drug Designation (ODD) for:
- ^{67}Cu SARTATE granted (neuroblastoma therapy)
- ^{67}Cu SARTATE granted (management of neuroblastoma)

RPDDs may potentially allow to access 2 Priority Review Vouchers, which are tradeable and have recently transacted at US$95M

SAR Therapy

SARTATE in neuroblastoma

CL04

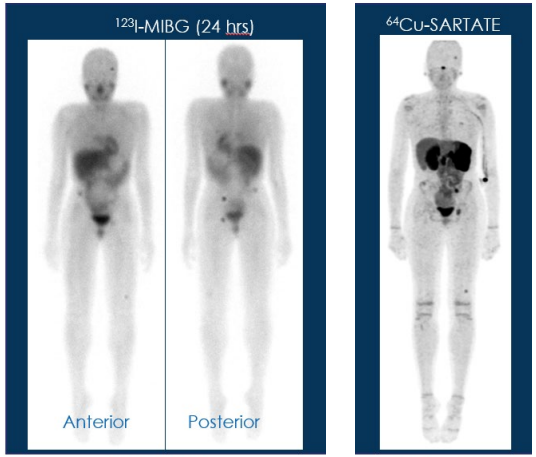
SARTATE CL04: ^{67}Cu-SARTATE Peptide Receptor Radionuclide Therapy Administered to Pediatric Patients With High-Risk, Relapsed, Refractory Neuroblastoma

CL04: ^{64}Cu/^{67}Cu SARTATE Phase I/IIa trial in high-risk neuroblastoma in the US with up to 34 patients

Trial Design

Multi-centre, dose-escalation/dose-expansion, open label, non-randomised, theranostic clinical trial

CL04 patient dosed with 12.4GBq Cu-67 SARTATE in Feb 23

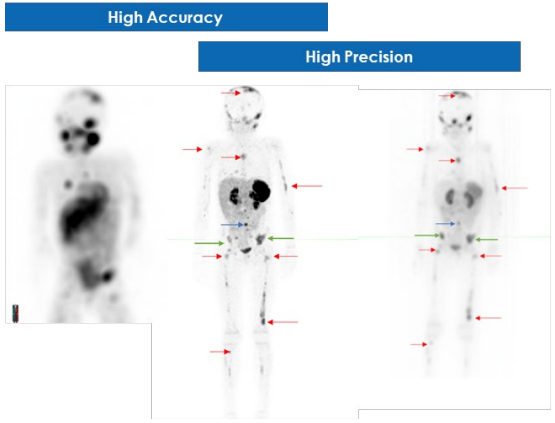


5 Jan 2023
Whole Body Scan (WB)

24 Jan 2023

Status

- Cohort 1 complete, no safety issues (3 patients) 75MBq/kg b.w.
- Cohort 2 complete, no safety issues (3 patients) 175MBq/kg b.w.
- Cohort 3 ongoing, no safety issues to date 275MBq/kg b.w.
- Recruiting at multiple sites in the US



CLARITY PHARMACEUTICALS

CL04 ClinicalTrials.gov identifier: NCT04023331

SAR-bisPSMA in prostate cancer

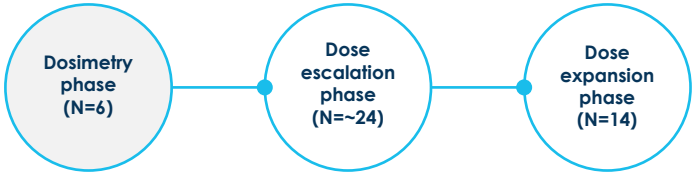
70 - 008

SECuRE: Systemic Copper theranostics in prostate cancer

- Phase I/IIa study of ^{64}Cu/^{67}Cu SAR-bisPSMA for identification and treatment of PSMA-expressing metastatic castrate resistant prostate cancer (mCRPC)
- Dose escalation phase aims to find the highest dose of ^{67}Cu SAR-bisPSMA that can be given safely and expand patient numbers at that dose in dose expansion

Trial design

Theranostic multi-centre, single arm, dose escalation study with a cohort expansion planned for up to 44 patients



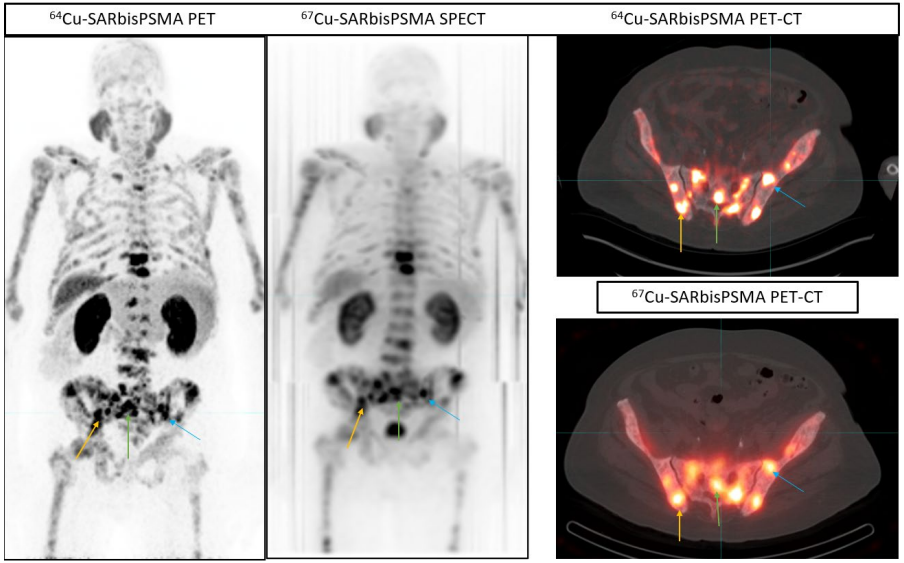
Status

- Dosimetry phase with ^{64}Cu SAR-bisPSMA in mCRPC completed
- Dose escalation phase underway

Next milestone

- Advance to next dose cohort

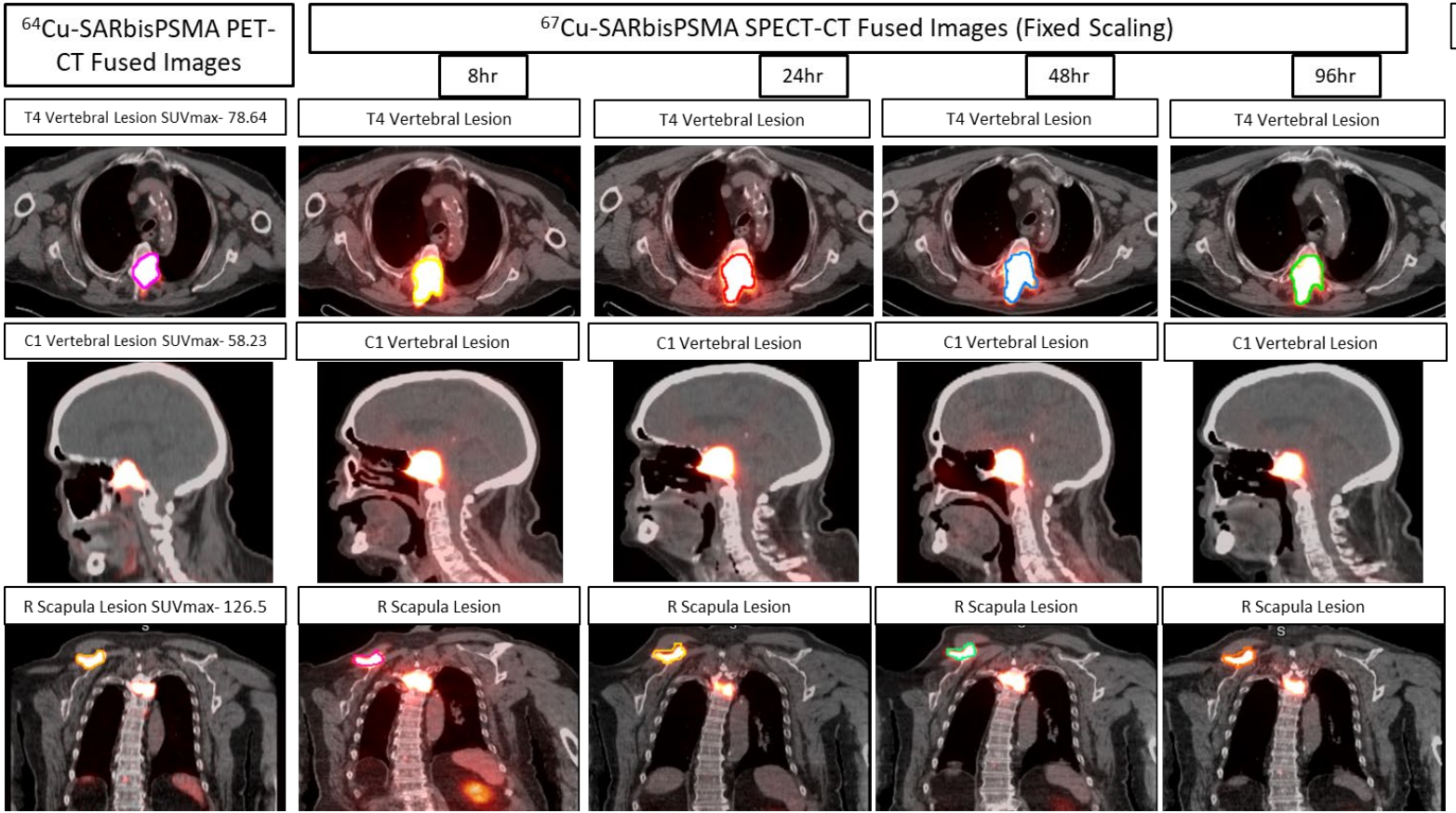
Comparison of ^{64}Cu SAR-bisPSMA and ^{67}Cu SAR-bisPSMA in Patient 70-008



SECuRE clinicaltrials.gov identifier: NCT04868604

Images: Cohort 1 (4GBq dosage level)

SECuRE

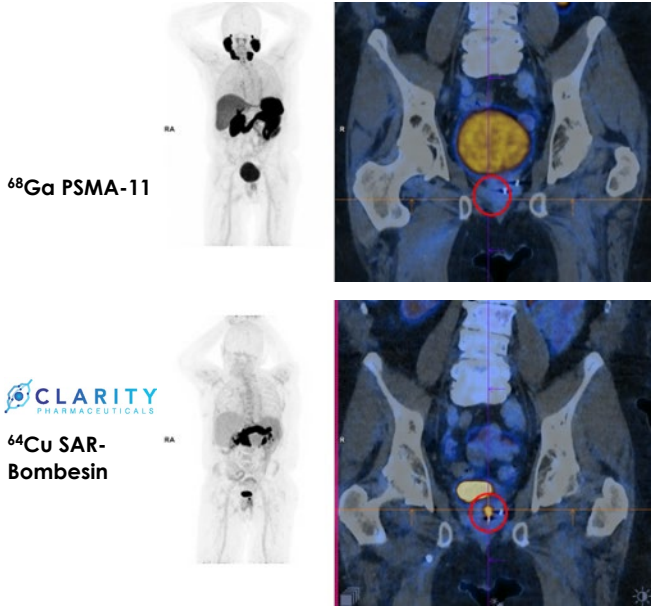


SAR-Bombesin in prostate cancer

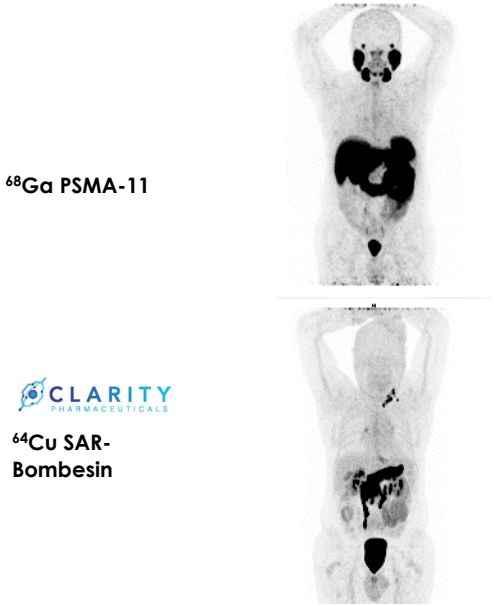
GRPr is a receptor that is overexpressed in a number of cancers including prostate, breast, colon, gastric, glioma, pancreatic, small cell lung and non-small cell lung cancer, as well as renal cell cancer

- **75%-100% of prostate cancers express GRPr**
- **~20%** of prostate cancer patients do not **express PSMA**
- PSMA negative prostate cancer patients will not respond to PSMA imaging or therapy
- SAR-Bombesin is now under investigation as a theranostic as well as a stand-alone diagnostic imaging agent for PSMA-negative prostate cancer

SAR-Bombesin was able to locate tumours in PSMA-negative prostate cancers that are not visible with approved PSMA diagnostics



^{68}Ga PSMA-11 (top) images of a PSMA-negative patient with clinical signs of prostate cancer (a rising PSA score of 0.16 ng/mL) and ^{64}Cu SAR-Bombesin PET/CT images of the same patient (bottom)



^{68}Ga PSMA-11 (top) image of a PSMA-negative patient with history of prostate cancer (a rising PSA score of 25 ng/mL) and ^{64}Cu SAR-Bombesin PET/CT image of the same patient (bottom)

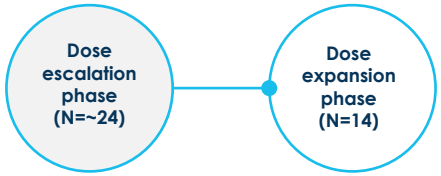
^{67}Cu SAR-Bombesin in prostate cancer

COMBAT: Copper-67 SAR Bombesin in metastatic castrate resistant prostate cancer

- A Phase I/IIa theranostic study of ^{64}Cu-SAR-BBN and ^{67}Cu-SAR-BBN for identification and treatment of GRPR-expressing metastatic castrate resistant prostate cancer in patients who are ineligible for therapy with ^{177}Lu-PSMA-617

Trial design

Theranostic multi-centre, single arm, dose escalation study with a cohort expansion planned for up to 38 patients

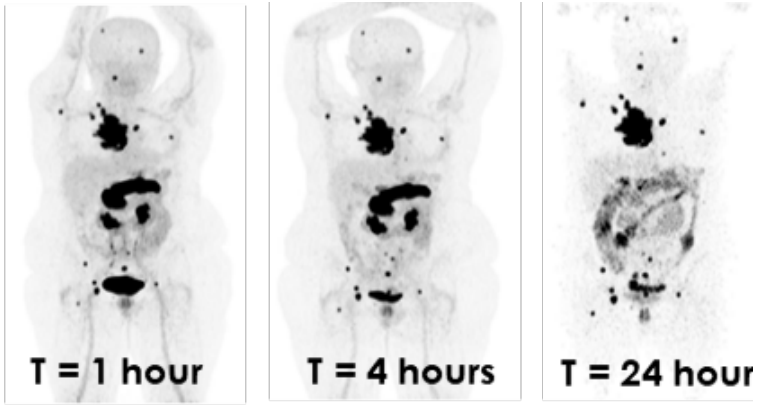


Status

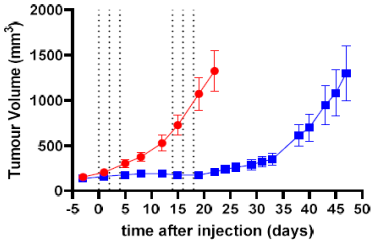
- Currently on track for 1st patient in Q2 23

^{64}Cu SAR-BBN in C-BOBCAT study

^{64}Cu SAR-Bombesin is retained in the tumours while quickly clearing from the pancreas in hormone positive metastatic breast cancer



Efficacy of Cu SAR-Bombesin in a mouse model of prostate cancer



Control group
^{67}Cu-SAR-Bombesin treated group

^{67}Cu SAR-Bombesin has demonstrated an anti-tumour effect in preclinical models of prostate cancer, when compared to the control group

SAR Diagnostics

Cu-64 will become the isotope of choice for PET imaging by overcoming the clinical and operational challenges with Ga-68 and F-18 based diagnostics

	Challenges with approved Ga-68 and F-18 based diagnostics	Solutions provided by Cu-64 based diagnostics
Ideal physical characteristics for imaging	• Short half-life of Ga-68 and F-18 does not allow for clinically relevant delayed imaging, which limits their diagnostic utility • Long positron range of Ga-68 leads to lower image quality	• Optimal half-life of 12.7 hours and proprietary SAR chelator allows for delayed imaging and increased diagnostic utility • Short positron range of Cu-64 leads to improved imaging resolution relative to Ga-68
Significant manufacturing & logistical advantages	• Expensive network of 3rd party cyclotrons and/or radiopharmacies are required due to short half-lives of Ga-68 and F-18 • Extensive resources, investments and partnerships with 3rd parties are needed to scale capacity and reach of Ga-68 and F-18 diagnostic agents	• Commercial supply for North America from a single manufacturing site • Longer shelf-life of Cu-64 allows for the development of production redundancies which are impossible with shorter lived agents like Ga-68 and F-18 • Fast launch trajectory as single production site can supply all imaging centres in the US at approval
User-friendly products for clinicians and patients	• Short half-lives create logistical and patient care challenges for imaging centres as there is a limited timeframe to administer the diagnostic agent and image the patient • Limited patient access in rural areas based on distribution range of F-18 and Ga-68 diagnostics • As utilisation of diagnostics increases, it creates cumulative occupational safety constraints for safety for patients, clinicians and staff	• Immediate national availability and access makes Cu-64 ideal for the widely distributed community oncology setting which is where 80% of cancer patients currently receive their care in the US • Delivered as a ready-to-use cGMP product with no need for sites to invest in expensive generators, radiopharmacies or specialised personnel • Product shelf-life of up to 48 hours gives sites increased flexibility for scheduling patients • Imaging timepoints from 1 to 72 hours gives sites operational flexibility in managing patient flow and PET scanner availability • 9-22 times lower radiation exposure than commonly used F-18 diagnostics on a per patient level, leading to increased radiation safety for patients, clinicians and staff

The future leader of the PET radioisotope market must have supply that is **dependable, scalable and customer focused**

SAR-bisPSMA diagnostic development

Two Phase III trials required for registration in prostate cancer: one in the pre-definitive treatment and one in the biochemical recurrence (BCR) setting. Clarity is expecting to commence registrational trials in 2023.

PROPELLER

Pre-definitive treatment

- Phase I multi-centre, blinded review, dose ranging, non-randomised study in 30 patients
- FIH study performed in Australia
- Results at ASCO GU

- Initiating Phase III study in the US during 2023

COBRA

Biochemical recurrence

- Phase I/II multi-centre, single arm, non-randomised study in up to 50 patient
- Performed under IND in the USA
- Recruitment complete, patients in 6M follow up

- Anticipate Initiating Phase III study in the US during 2024

PSMA diagnostics are set to become a blockbuster market with >$1.6B in the US

CLARITY PHARMACEUTICALS

PROPELLER clinicaltrials.gov identifier: NCT04839367

COBRA clinicaltrials.gov identifier: NCT05249127

Positron Emission Tomography of Patients with Confirmed Prostate Cancer Using ^{64}Cu-SAR-bisPSMA: results from PROPELLER

Eva Lengyelova[1], Veronica Wong[2], Nat Lenzo[3], Michelle Parker[1], Louise Emmett[4]

[1] Clarity Pharmaceuticals, Sydney, Australia; [2] Nepean Hospital, Sydney, Australia; [3] GENESISCARE East Fremantle, Australia; [4] St. Vincent's Hospital, Sydney, Australia

Corresponding Author: Louise.Emmett@svha.org.au

Background

Prostate-Specific Membrane Antigen (PSMA) is a type II transmembrane glycoprotein that is overexpressed in prostate cancer (PC).

Advantages of ^{64}Cu-SAR-bisPSMA over ^{68}Ga-PSMA-11 PET:

- the targeting moiety has two PSMA-targeting functional groups which can lead to improved tumor uptake and retention;
- the copper-64 (^{64}Cu) isotope has a longer half-life ($t_{1/2}$: 12.7h), allowing a 1-72h scan acquisition window, longer shelf-life, greater flexibility for patient scheduling and may translate into detection of additional lesions; and
- ^{64}Cu has a shorter positron range (0.56mm), leading to improved scan resolution.

PROPELLER (NCT04839367) was a Phase 1, multi-center, blinded review, dose-ranging study evaluating safety and preliminary efficacy of ^{64}Cu-SAR-bisPSMA PET in patients with known primary PC.

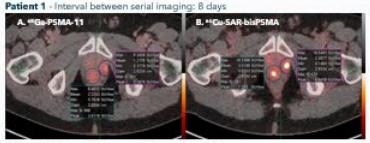
The aim of PROPELLER was to:

- determine the safety and tolerability of ^{64}Cu-SAR-bisPSMA;
- determine the ability of ^{64}Cu-SAR-bisPSMA PET to detect primary PC;
- assess image quality at 100, 150 and 200 MBq dosages of ^{64}Cu-SAR-bisPSMA; and
- explore how ^{64}Cu-SAR-bisPSMA compares to ^{68}Ga-PSMA-11 PET, a standard-of- care (SOC) radiotracer for imaging of PSMA-positive lesions in PC.

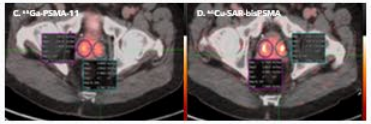
Imaging results

Figure 1. Intra-individual comparison of ^{68}Ga-PSMA-11 (A,C) and 200 MBq of ^{64}Cu-SAR-bisPSMA (B,D) PET/CT.

Patient 1 - Interval between serial imaging: 8 days

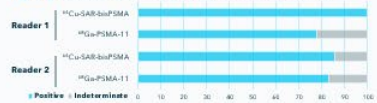


Patient 2 - Interval between serial imaging: 34 days



^{64}Cu-SAR-bisPSMA shows clearer delineation of lesions and higher SUVmax.

Figure 3. Primary PC PET results in the 200 MBq Dose Cohort (n=18)



PROPELLER

Phase 1 multi-center diagnostic trial

^{64}Cu-SAR-bisPSMA

A new frontier for prostate cancer imaging that is safe and efficacious for the detection of primary and secondary disease

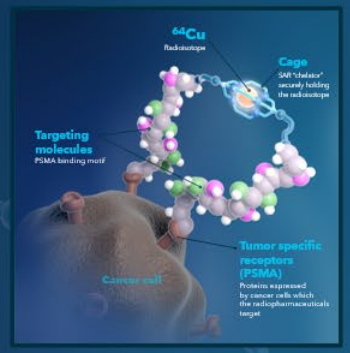
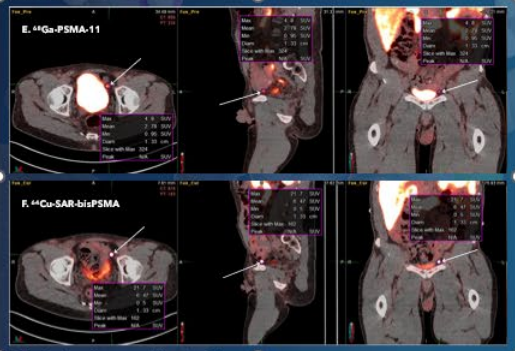


Figure 2.
PET/CT demonstrated uptake of ^{64}Cu-SAR-bisPSMA (F) in a left pelvic lymph node according to both readers and PC was confirmed via histopathology. Readers did not detect uptake in pelvic lymph nodes on the ^{68}Ga-PSMA-11 PET/CT (E).



Patient 3 - Interval between serial imaging: 7 days

Abstract #: PS18

Methods

Prospectively, **30 patients** with untreated, histopathologically proven, primary PC with intermediate- to high-risk features were included in the study.

At screening, patients completed a ^{68}Ga-PSMA-11 PET/CT between 45-60min post injection per SOC protocols.

Patients were dosed 1:1:3 with 100 MBq, 150 MBq and 200 MBq of ^{64}Cu-SAR-bisPSMA, followed by a PET/CT at 2-4h post injection.

Safety was evaluated pre and post dose for up to 11 weeks via adverse event (AE) reporting, vital signs, electrocardiograms, blood and urine analysis.

^{68}Ga-PSMA-11 and ^{64}Cu-SAR-bisPSMA PET/CT scans were evaluated by 2 independent, blinded, central readers for image quality, PC detection and intensity of tracer uptake in lesions (maximum Standardized Uptake Values [SUVmax]). Patients then proceeded to prostatectomy with pelvic lymph node dissection.

Table 1. Demographics and Baseline Characteristics (n=30)

Median (range) Age (years)	64 (50 to 75)	
TNM Stage	Unknown	2 (6.7%)
	T1a	1 (3.3%)
	T1c	3 (10.0%)
	T2a	7 (23.3%)
	T2b	5 (16.7%)
	T2c	9 (30.0%)
	T3a	3 (10/0%)
	T3b	1 (3.3%)
	N0	28 (93.3%)
ISUP Grade Group	2	3 (10.0%)
	3	12 (40.0%)
	4	7 (23.3%)
	5	8 (26.7%)
Mean (SD) PSA Level (ng/mL)	10.49 (8.08)	

Results

^{64}Cu-SAR-bisPSMA was well tolerated with only a single related AE of Grade 1 dysgeusia (metallic taste) reported in the 200 MBq cohort (**Table 2**). Interval between ^{68}Ga-PSMA-11 and ^{64}Cu-SAR-bisPSMA PET/CT scans was 2-50 days (median 20.5).

Table 2. Incidence of Treatment-Related AEs (n=30)

^{64}Cu-SAR-bisPSMA	Related Adverse Events n (%)
100 MBq (n=6)	0 (0.0%)
150 MBq (n=6)	0 (0.0%)
200 MBq (n=18)	1 (5.6%)
All Participants (n=30)	1 (3.3%)

For both readers, 200 MBq of ^{64}Cu-SAR-bisPSMA scored the highest in terms of image quality. In this cohort, ^{64}Cu-SAR-bisPSMA and ^{68}Ga-PSMA-11 were able to detect primary PC in 100% and 77.8% of patients for Reader 1 and 85.7% and 83.3% of patients for Reader 2, respectively. The rest of the scans were indeterminate, no scan was deemed negative (**Table 3, Figure 3**).

Table 3. Primary PC PET results in the 200 MBq Dose Cohort (n=18)

Reader	^{64}Cu-SAR-bisPSMA PET			^{68}Ga-PSMA-11 PET		
	Positive	Negative	Indeterminate	Positive	Negative	Indeterminate
1	18/18	0/18	0/18	14/18	0/18	4/18
2	12/14*	0/14*	2/14*	15/18	0/18	3/18

*4 scans were excluded by the reader deeming them non-evaluable.

The resulting True Positive Rate (TPR) and False Negative Rate (FNR) were similar for ^{64}Cu-SAR-bisPSMA and ^{68}Ga-PSMA-11 PET/CT (**Table 4**). Uptake of ^{64}Cu-SAR-bisPSMA showed higher SUVmax compared to ^{68}Ga-PSMA-11 (**Figure 1**). Additional secondary disease, in a pelvic lymph node, was detected on ^{64}Cu-SAR-bisPSMA PET/CT compared to ^{68}Ga-PSMA-11 PET/CT and verified by histopathology (**Figure 2**).

Table 4. Detection of Primary PC in the 200 MBq Dose Cohort (n=18)

Reader	^{64}Cu-SAR-bisPSMA PET		^{68}Ga-PSMA-11 PET		P-value[2]
	% TPR (95% CI)	% FNR* (95% CI)	% TPR (95% CI)	% FNR* (95% CI)	
1	100.0 (81.5; 100.0)	0.0 (0.0; 18.5)	77.8 (52.4; 93.6)	22.2 (6.4; 47.6)	0.13
2	85.7 (57.2; 98.2)	14.3 (1.8; 42.8)	83.3 (58.6; 96.4)	16.7 (3.6; 41.4)	1.0

[1] Indeterminate results were analyzed as negative.
[2] McNemar's Chi-squared test with continuity correction.

Conclusions

^{64}Cu-SAR-bisPSMA, a new candidate for PC imaging, is shown to be safe, well-tolerated and efficacious for imaging PSMA-expressing lesions.

A dose of 200 MBq was determined as the optimal dose for future trials.

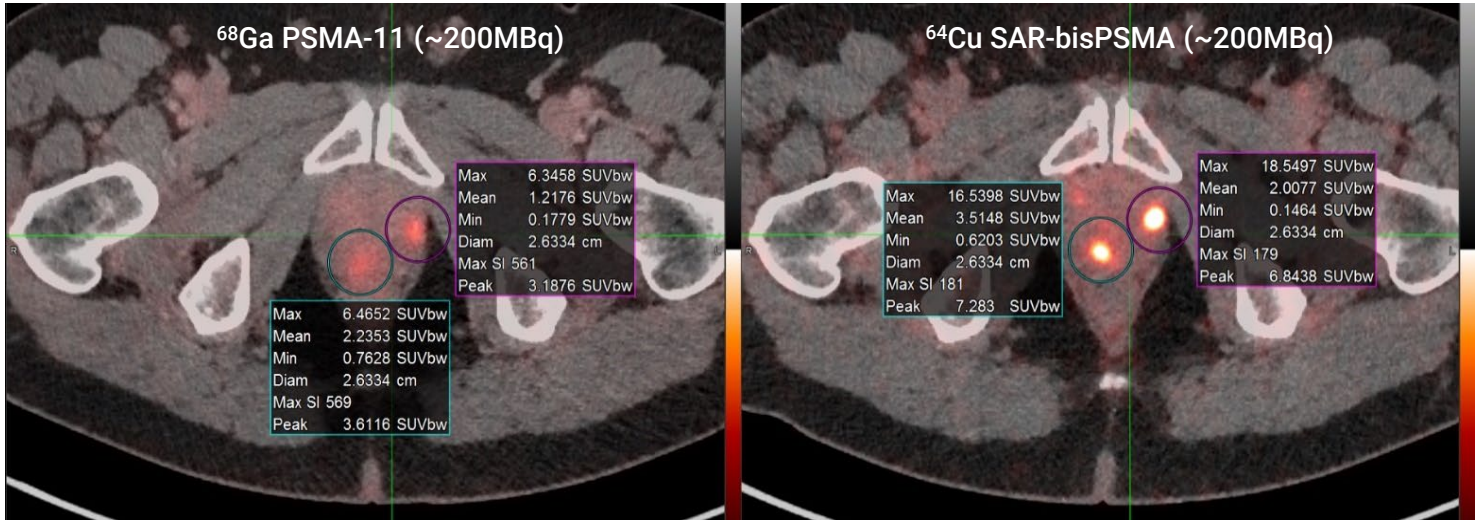
Further studies to evaluate ^{64}Cu-SAR-bisPSMA as an imaging agent in biochemical recurrence of PC are underway.

CLARITY PHARMACEUTICALS

SAR-bisPSMA diagnostic in untreated, confirmed prostate cancer

PROPELLER

Comparison of ^{68}Ga PSMA-11 (image left) to Clarity's ^{64}Cu SAR-bisPSMA (image right) in the same patient



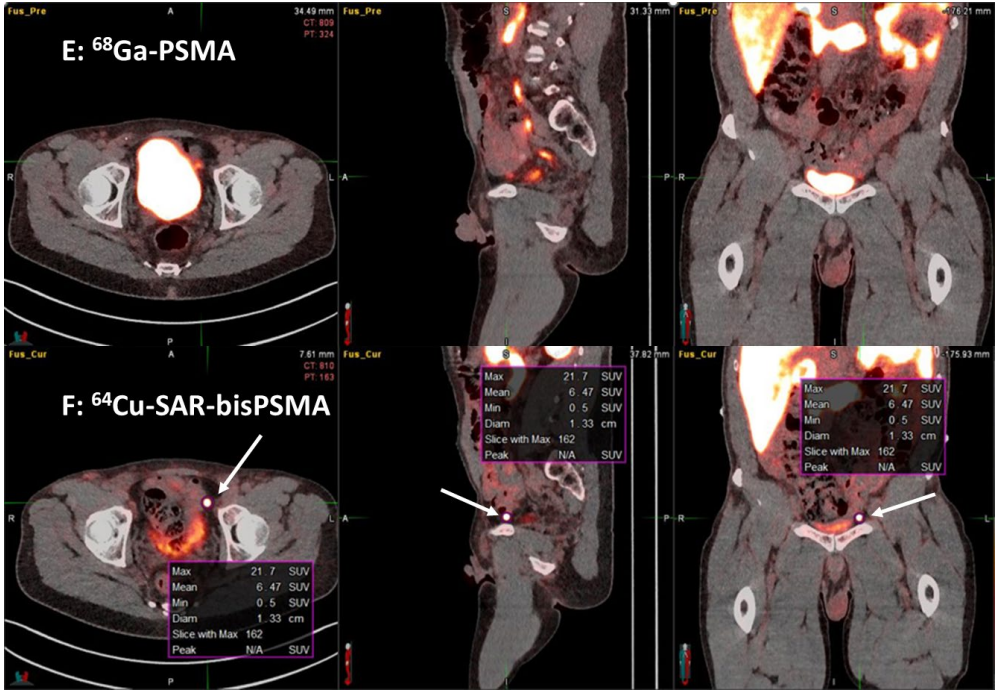
^{68}Ga PSMA-11 (~200MBq, left) vs. ^{64}Cu SAR-bisPSMA (~200MBq, right) in the same patient; time between serial imaging was 8 days. Standardised Uptake Value (SUVmax)* of the lesions were 6.5 and 6.3 for ^{68}Ga PSMA-11 and 16.5 and 18.5 for ^{64}Cu SAR-bisPSMA.

**SUV is a measurement of product uptake in tissue normalised to a distribution volume*

SAR-bisPSMA diagnostic in untreated, confirmed prostate cancer

PROPELLER

PET/CT demonstrated uptake of ^{64}Cu-SAR-bisPSMA (F) in a left pelvic lymph node according to both readers and PC was confirmed via histopathology. Readers did not detect uptake in pelvic lymph nodes on the ^{68}Ga-PSMA-11 PET/CT (E). Time between serial imaging was 7 days.



SAR-bisPSMA diagnostics

COBRA

COBRA: Copper-64 SAR-bisPSMA in BCR prostate cancer

- Phase I/II multi-centre, single arm, non-randomised study in up to 50 patients across the US
- Investigates the safety and tolerability of ^{64}Cu-SAR-bisPSMA as well as its ability to correctly detect recurrence of prostate cancer in participants with BCR of prostate cancer following definitive therapy

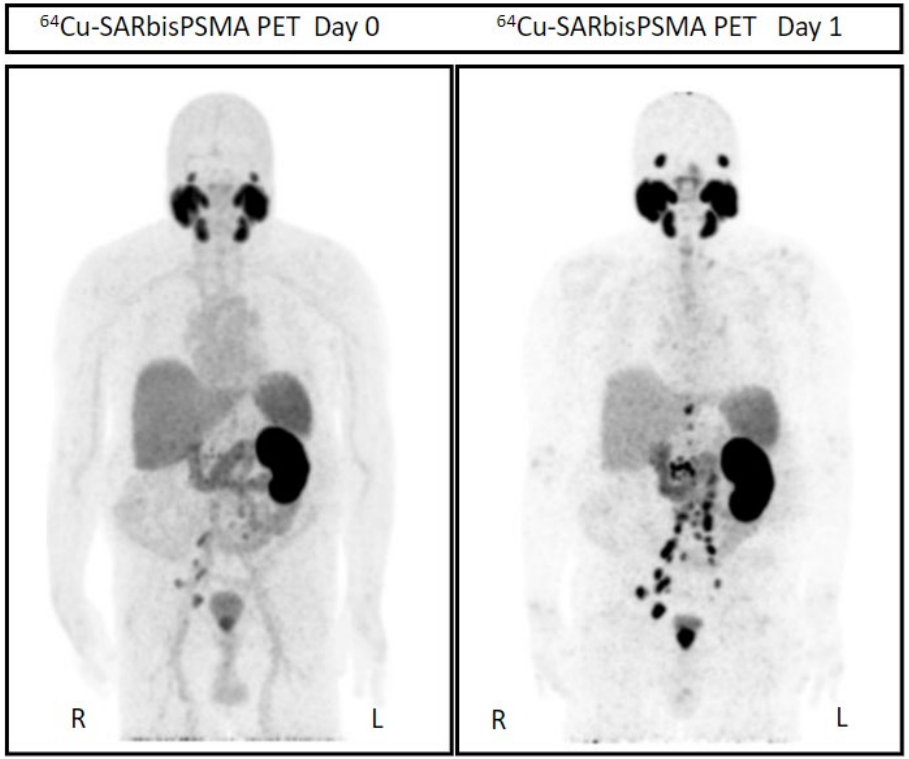
Trial design

Status

- Recruitment complete 09 February 2023

Next milestone

- 6 month follow up Topline results and data readout



Local assessment reported additional lesions on Day 1 compared to Day 0. Histopathology performed on one lesion returned a positive result for PC. Central review against Standard of Truth has not yet been carried out.

CLARITY

COBRA clinicaltrials.gov identifier: NCT05249127

SAR-Bombesin in PSMA-negative prostate cancer

SABRE: Copper-64 SAR-BBN in Biochemical Recurrence of prostate cancer

- **Phase II** Positron Emission Tomography (PET) imaging trial of participants with PSMA-negative biochemical recurrence (BCR) of prostate cancer following definitive therapy.
- The primary objectives of the trial are to investigate the safety and tolerability of the product as well as its ability to correctly detect recurrence of PSMA-negative prostate cancer.

Trial design

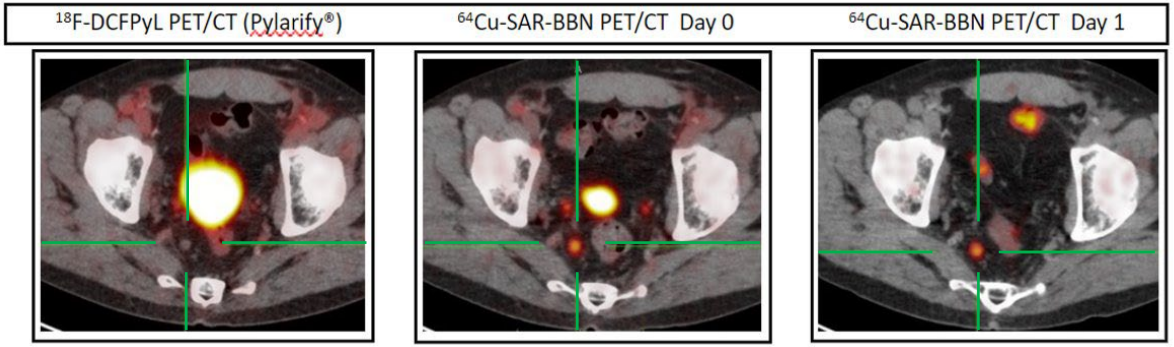
- Multi-centre, single arm, non-randomised, open-label trial of ^{64}Cu-labelled SAR-Bombesin in 50 participants.

Status

- Recruitment ongoing in the US

Next Milestone

- 50% recruitment in Q2 2023



Single pelvic lymph node uptake seen on ^{64}Cu SAR-BBN on both Day 0 and Day 1. Participant has been referred for biopsy, results pending. Participant has entered the follow-up period per protocol.

SABRE ClinicalTrials.gov identifier: NCT05407311

SAR-Bombesin in PSMA-negative prostate cancer

BOP

BOP IIT: Copper-64 SAR Bombesin in Prostate Specific Membrane Antigen (PSMA) negative Prostate Cancer

- Assesses the safety of ^{64}Cu-SAR-Bombesin and looks at the diagnostic potential across two different groups of men:
- Participants with suspected biochemical recurrence (BCR) of their prostate cancer who have negative PSMA positron emission tomography (PET) imaging scans or low PSMA expression disease
- Participants with metastatic castrate resistant prostate cancer (mCRPC) who are not eligible for PSMA therapy

Trial design

- **Phase II** investigator-initiated trial (IIT) led by Prof Louise Emmett at St Vincent's Hospital, Sydney

Status

- 50% recruited as of 02/11/22

Next Milestone

- 100% recruitment in Q3 2023

CLARITY

BOP ClinicalTrials.gov identifier: NCT05613842

SARTATE

DISCO: Diagnostic Imaging Study of Copper-64 SARTATE using PET on patients with known or suspected NETs

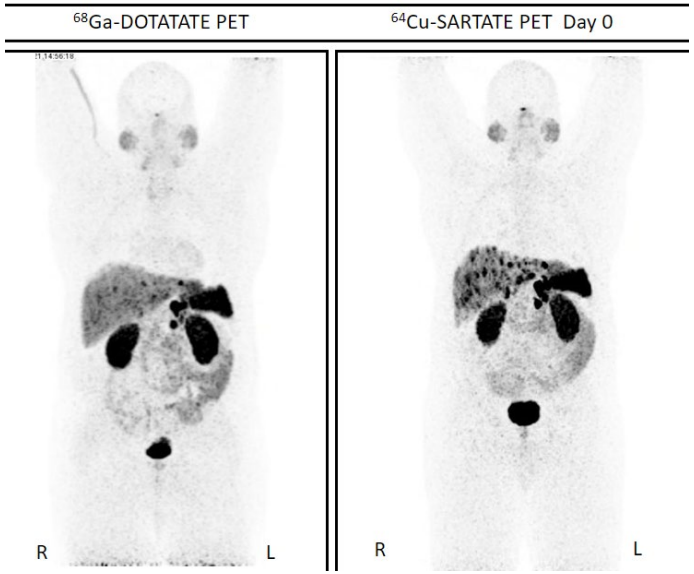
- Assesses the performance of imaging agent ^{64}Cu SARTATE in participants with known or suspected gastroenteropancreatic NETs as a potential new way to help diagnose and manage NETs
- Aims to capture and highlight the significant advantages of the longer half-life (12.7 hours) of copper-64, related to imaging and product supply which are relevant to Clarity's entire pipeline of products in development

Trial design

- Phase II multi-centre, single arm, non-randomised, blinded-review study in up to 63 participants
- Compares diagnostic performance of ^{64}Cu SARTATE™ at 4 and 20 hours to the current standard of care, ^{68}Ga DOTATATE, at 1 hour

Status

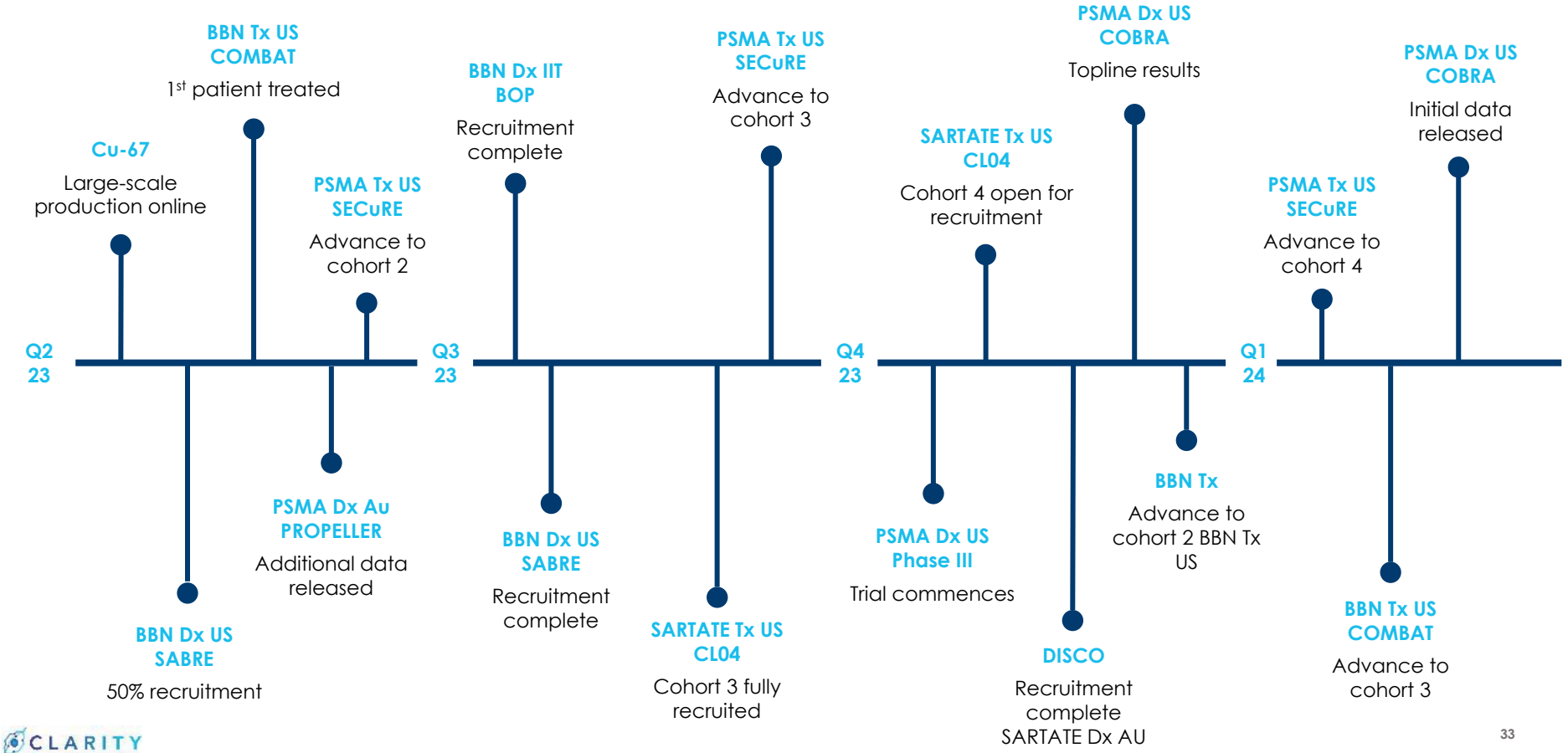
- Recruitment at 50% in Feb 2023



Local assessment has reported a higher number of lesions on ^{64}Cu-SARTATE compared to ^{68}Ga-DOTATATE. Interval between scans was 1 day.

Inflection points in the next 12 months

Dx = Diagnostics
Tx = Theranostics



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

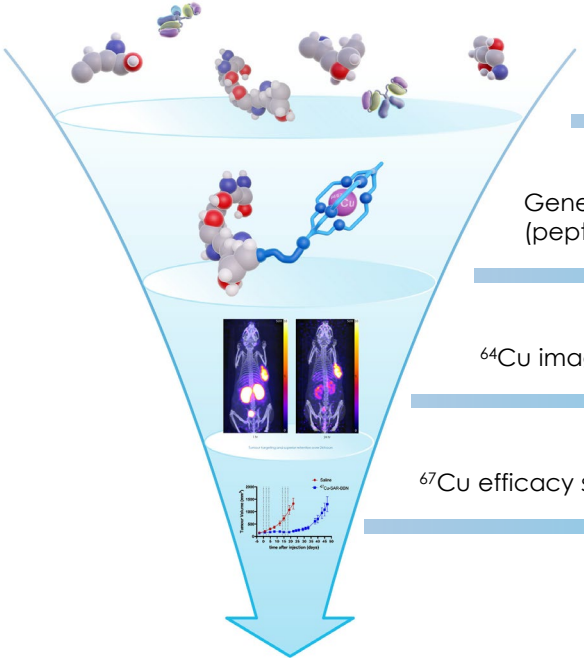
Pipeline Protection

- 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

Discovery Engine



Select high value cancer targets

Generate and radiolabel compounds (peptides and/or antibodies)

^{64}Cu imaging in tumour models

^{67}Cu efficacy studies in tumour models

SAR Technology platform

High value clinical candidates: SARTATE™, SAR-bisPSMA, SAR-Bombesin, etc.

Highly experienced team

Dr Alan Taylor
Executive Chairman

Dr Colin Biggin
CEO

Michelle Parker
EVP – Global Clinical Operations

Shaemus Gleason
EVP - Operations

Dr Jennifer Rosenthal
Director of Quality & Regulatory Affairs

Dr Matt Harris
Director of Technology

Dr Jeff Norenberg
Chief Scientific Officer

Robert Vickery
Company Secretary

David Green
Chief Financial Officer

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

ALGETA NOVARTIS CardinalHealth™ BAYER Viralytics Developers of Oncolytic Immunotherapies invicro

CLARITY

Board of Directors

Clarity's board has extensive capital markets, radiopharmaceutical and broader life sciences experience

Dr Alan Taylor
Executive Chairman

Rosanne Robinson
Non-Executive Director

Ms Robinson brings extensive experience in the nuclear field and a range of commercial expertise to the Company and has over 25 years of experience in both governance and management roles in public and private companies and government.

Dr Thomas Ramdahl
Non-Executive Director

Dr Ramdahl is a pharmaceutical executive with over 20 years of clinical and development experience. He was President and the first CEO of Algeta ASA, serving in several senior positions through to and post the acquisition of Algeta by Bayer AG in 2014 for US$2.9 billion.

Cheryl Maley
Non-Executive Director

Ms Maley is an experienced senior leader with over 25 years of experience in the pharmaceutical industry. She has a strong strategic, commercial background with a proven track record in product launch excellence and timely patient access to innovative medicines.

Dr Colin Biggin
Managing Director

Dr Chris Roberts
Non-Executive Director

Dr Roberts has over 40 years of experience in the medical innovation space and has served on the boards of a number of ASX-listed companies during his career.

Mr Robert Thomas
Non-Executive Director

Mr Thomas has a strong background in financial services and capital markets including advising on the IPOs of the Commonwealth Bank of Australia and Qantas.

Clarity's Advisory Board

Clarity's advisory board comprises global thought leaders with extensive capabilities, expertise and experience in developing radiopharmaceuticals

Prof Oliver Sartor

Medical oncologist and an internationally recognised expert in prostate cancer. He is the Laborde Professor for Cancer Research, Medical Director of the Tulane Cancer Center, and Assistant Dean for Oncology at Tulane University School of Medicine in New Orleans, Louisiana.

Prof Richard Wahl

The Elizabeth Mallinckrodt Professor, Chairman of the Department of Radiology and Director of the Mallinckrodt Institute of Radiology at Washington University School of Medicine in St Louis.

Prof Jason Lewis

The Emily Tow Jackson Chair in Oncology and serves as Vice Chair for Research in the Department of Radiology at Memorial Sloan Kettering Cancer Center (MSK), Chief of MSK's Radiochemistry & Imaging Sciences Service, and Director of MSK's Radiochemistry and Molecular Imaging Probe Core Facility.

Prof Andreas Kjaer

A professor at the University of Copenhagen and a chief physician at the Department of Clinical Physiology, Nuclear Medicine & PET at Rigshospitalet, the National University Hospital of Denmark.

Dr Andrei Iagaru

An award-winning Professor of Radiology - Nuclear Medicine and the Chief of the Division of Nuclear Medicine and Molecular Imaging at Stanford University. His research focus includes PET/MRI and PET/CT imaging for early cancer detection as well as peptide-based diagnostic imaging and therapy.

Dr Neal Shore

CMO of Urology/Surgical Oncology at GenesisCare, US and the Medical Director of Carolina Urologic Research Centre. He has conducted more than 400 clinical trials with a particular focus on GU oncology indications and is an internationally recognised expert and researcher in systemic therapies for patients with advanced urologic cancers.

Prof Paul Donnelly

The Clarity Group leader of the Donnelly Research Group, The University of Melbourne, based in the state-of-art laboratories of the Bio21 Institute of Molecular Science and Biotechnology.

Prof Louise Emmett

Director of Theranostics and Nuclear Medicine at St Vincent's Hospital Sydney, a conjoint professor of medicine at the University of New South Wales and clinical research leader at the Garvan Institute of Medical Research.

Jon Stoner

Director of the Idaho Accelerator Center at Idaho State University. He has been researching isotope production using linear accelerators for 14 years and pioneered a new process and mechanism for producing copper-67

Summary

Global leader in Targeted Copper Theranostics (TCTs)

- **Extensive pipeline** of TCTs based on ^{64}Cu for diagnosis and ^{67}Cu for therapy
- Seven clinical trials and an IIT in development with **Phase III clinical trials commencing from 2023**
- 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**
- Well funded with **~$83 million** to fund the existing trials and provide cash runway into 2024
- Led by **an experienced management team and Board** with significant years of active involvement in the radiopharmaceutical industry
- **Hot sector of the market** with numerous recent acquisitions.

Thank you

Contact details

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Managing Director
E: colin.biggin@claritypharm.com