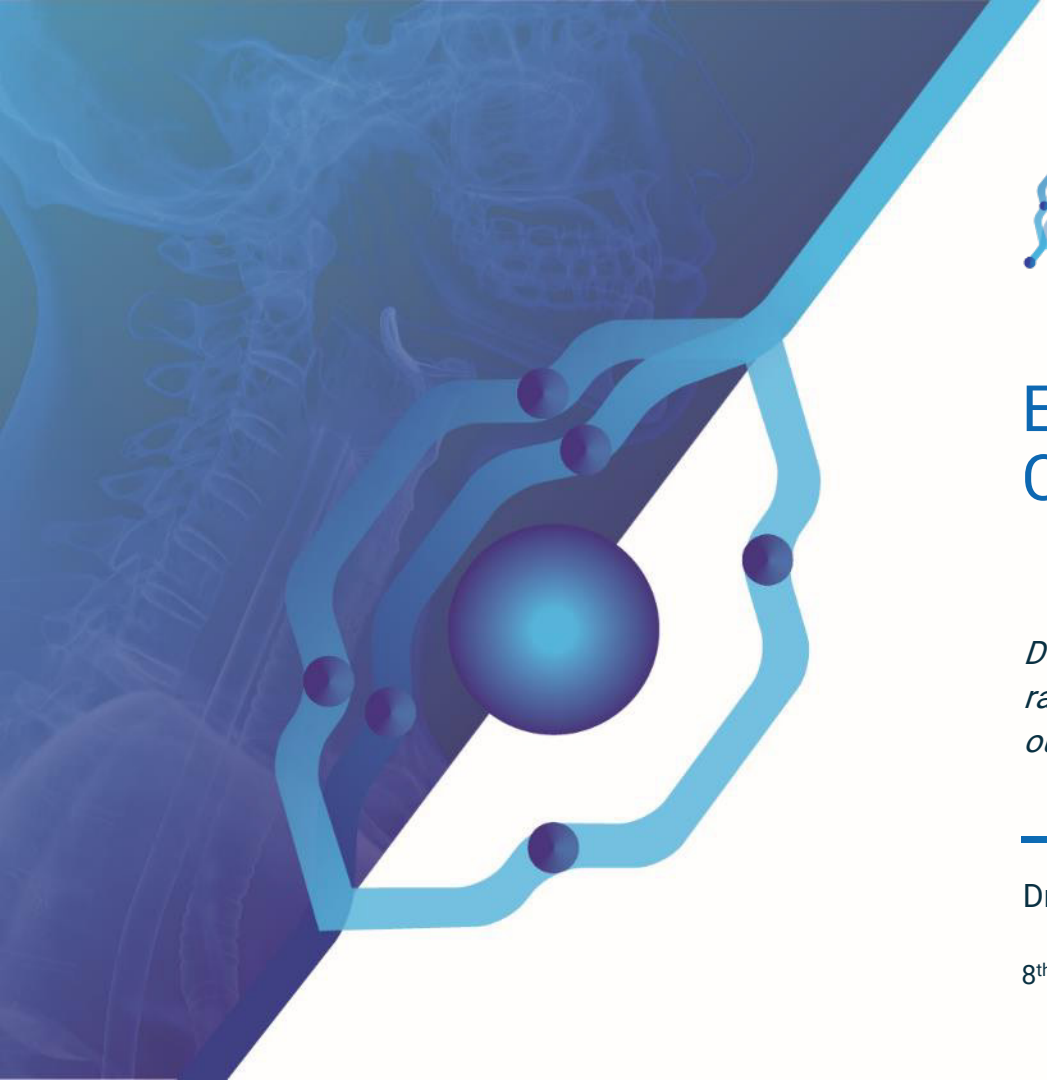

CLARITY PHARMACEUTICALS

E&P Small Cap Healthcare Conference

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

Dr Colin Biggin, Managing Director and CEO

8th September 2023

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Statements made in this presentation are made only as at the date of this presentation. The information in this presentation remains subject to change without notice. The Company may in its absolute discretion, but without being under any obligation to do so, update or supplement this presentation. Any further information will be provided subject to the terms and conditions contained in this Disclaimer.

Corporate Snapshot

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 of isotopes 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

Commercialisation of diagnostic products first, generating revenue to fund late-stage therapeutic trials

Highly experienced leadership team

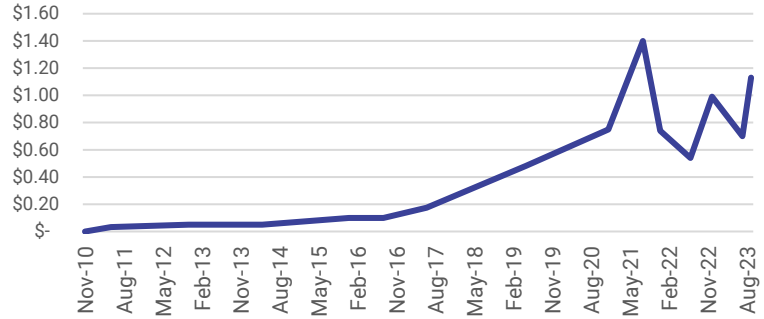
Diverse and in-depth expertise spanning corporate finance, operations, commercialisation & industry. Significant radiopharmaceutical experience across all functions

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	A$1.13
Cash at bank[1]	A$65M
Shares on issue	261.9M
Options on issue	26.3M
Market cap (undiluted)[2]	A$295.9M

1. As at 30 June 2023
2. As at 8 September 2023

Share price

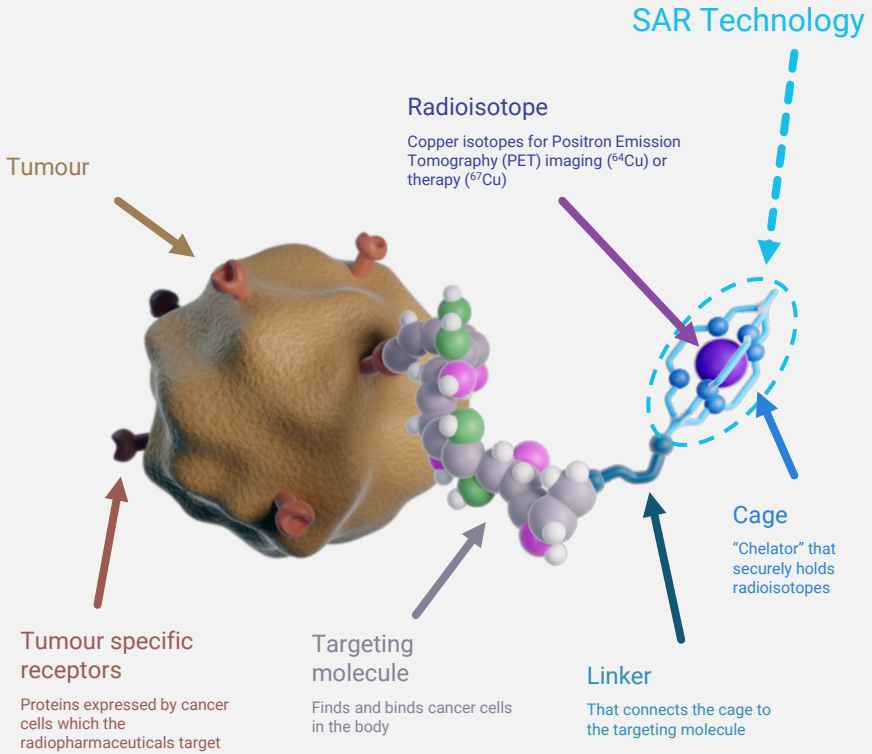


Clarity – The Copper Theranostics Company

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

Proprietary SAR Technology enables Targeted Copper Theranostics

- Clarity’s SAR technology is a proprietary, highly specific and highly stable bifunctional cage (chelator) with a superior ability to retain copper isotopes within it and prevent their leakage into the body
- TCT deliver a compelling combination of high accuracy and high precision in the treatment of a range of cancers, as well as providing supply and logistical advantages over current theranostics

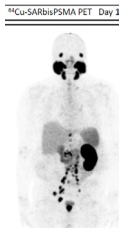


Why Copper?

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
Imaging 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	~0.7mm	~0.7 mm
Production mode	Electron accelerators	Nuclear reactors
Cost to scale supply	Low (~US$15M)	High (>US$1Bn)
Time to scale supply	Quick (<18 months)	Slow (>10 years)

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 in 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 loss of pass-through-status after 3 years in the US

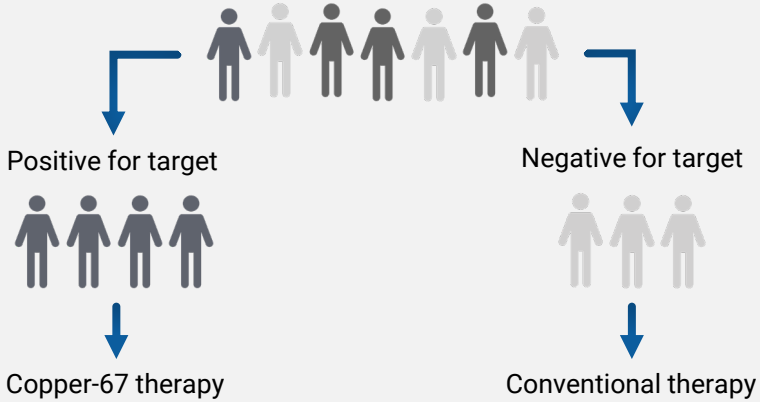
Future Dx revenue pays for late-stage Tx clinical development

Marketed Dx re-enforces Tx position

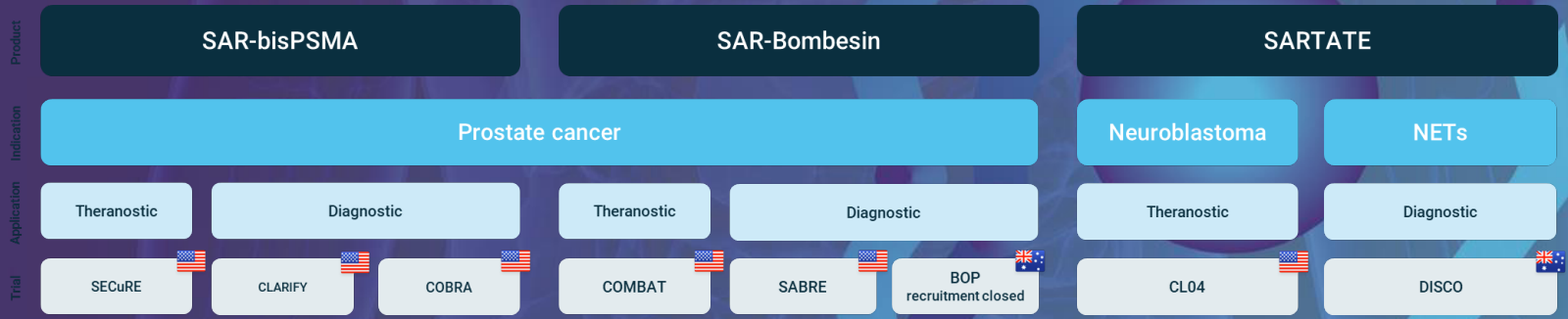
Theranostics based on ^{64}Cu/^{67}Cu

- 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



Three key product areas

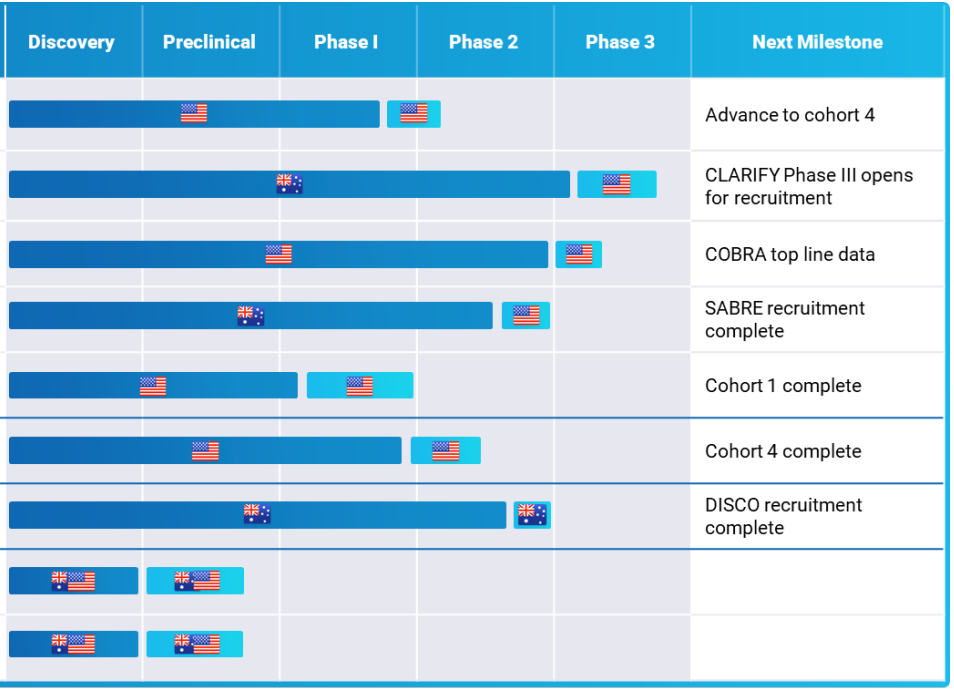


Clinical development in multiple cancers

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

Clinical development pipeline as of 8 September 2023

Indication	Product	Application	Current Trial	Next Milestone
Prostate Cancer	SAR-bisPSMA	Theranostic mCRPC	SECURE	Advance to cohort 4
	SAR-bisPSMA	Diagnostic in pre-radical prostatectomy	CLARIFY	CLARIFY Phase III opens for recruitment
	SAR-bisPSMA	Diagnostic in BCR PCa	COBRA	COBRA top line data
	SAR-BBN	Diagnostic in BCR PCa	SABRE	SABRE recruitment complete
	SAR-BBN	Theranostic mCRPC	COMBAT	Cohort 1 complete
Neuroblastoma	SARTATE™	Theranostic	CL04	Cohort 4 complete
NETs	SARTATE™	Diagnostic	DISCO	DISCO recruitment complete
SAR Discovery Platform	Undisclosed	Undisclosed		
	Undisclosed	Undisclosed		



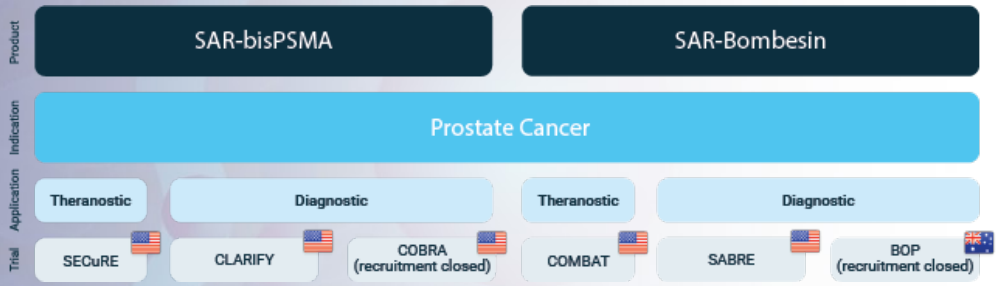
Note clinical development pipeline is indicative only, subject to review.

All US studies are conducted under IND

Prostate cancer

Two product areas: bisPSMA & Bombesin

Four products for diagnosis and therapy



Clarity's three areas of focus in prostate cancer

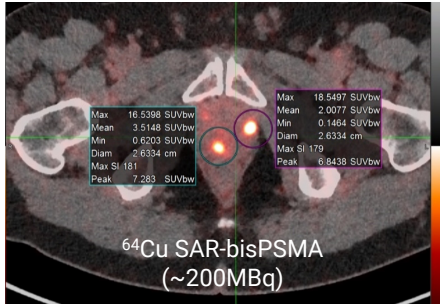
Prostate cancer is the second largest oncology indication in men; there are three stages of prostate cancer

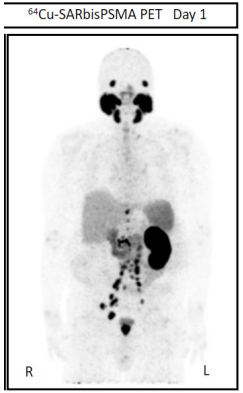
Primary → Biochemical recurrence (BCR) → Metastatic castration-resistant (mCRPC)

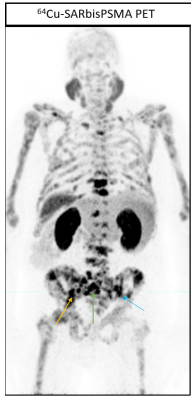
- PC localised in the prostate gland with a main (primary) tumour
- Unless the disease has spread, the most common treatment is a surgery called prostatectomy (removal of the prostate) or radiation therapy

- PC that persists after primary therapy
- Prostate-specific antigen (PSA) level rising indicates presence of PC
- Up to half of PC patients have BCR after primary curative therapy

- PC that spread beyond the prostate gland and is growing in other organs and tissues
- No longer responds to treatments that lower testosterone or to hormone therapy
- Form of advanced PC that shows signs of growth and a rising PSA level





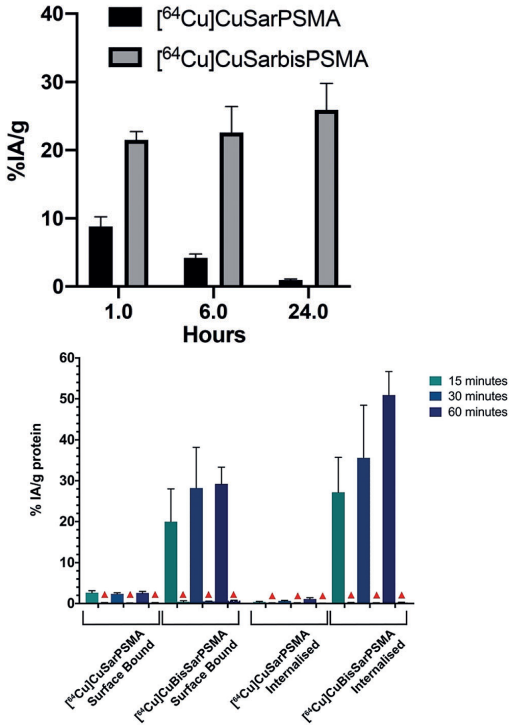


^{64}Cu SAR-Diagnostics

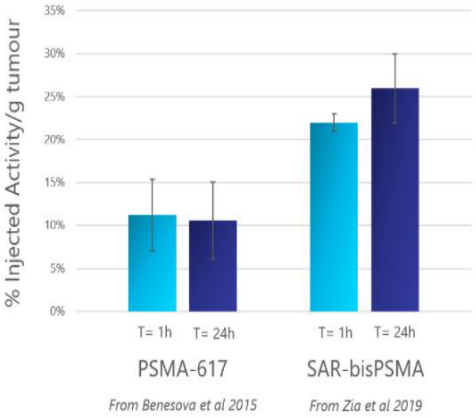
^{67}Cu SAR-Therapy

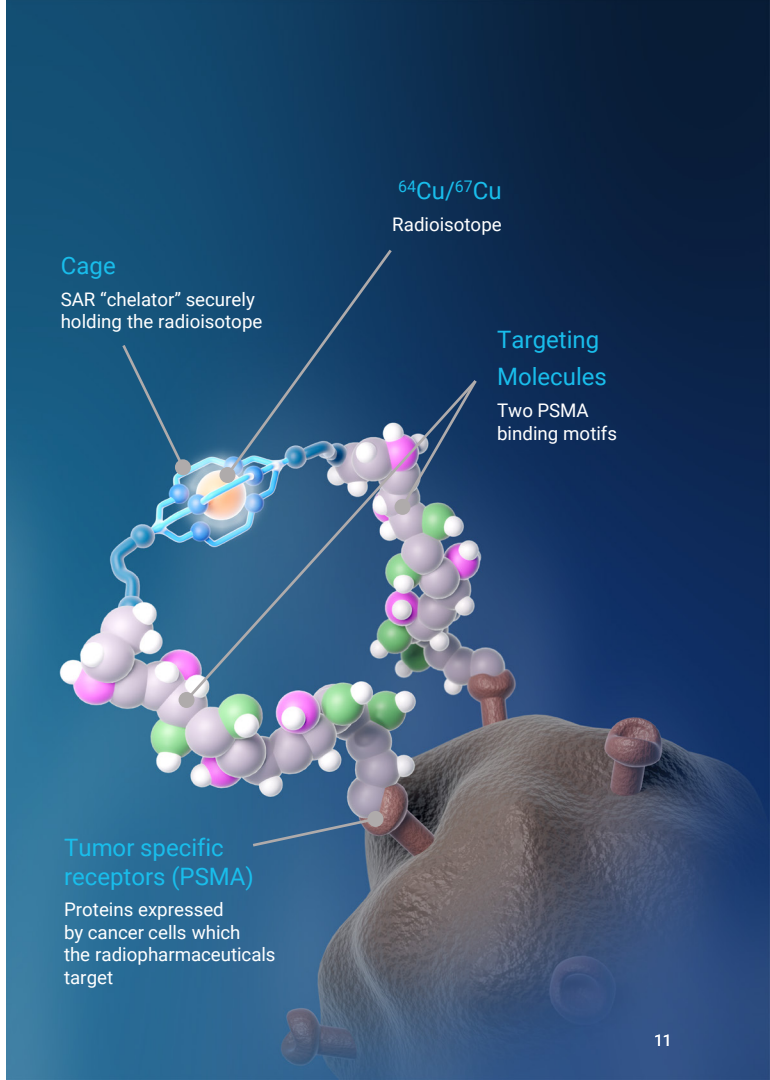
SAR-bisPSMA

Superior performance of bisPSMA compared to monomer PSMA



bisPSMA has higher uptake in tumours and strong retention compared to PSMA monomers





Zia et al., 2019. Ang.Chem

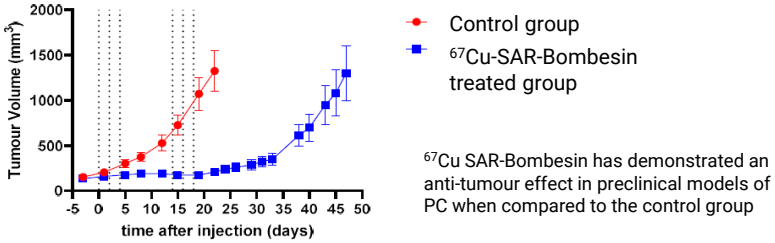
SAR-Bombesin

SAR-Bombesin targets Gastrin Releasing Peptide receptor (GRPr) 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

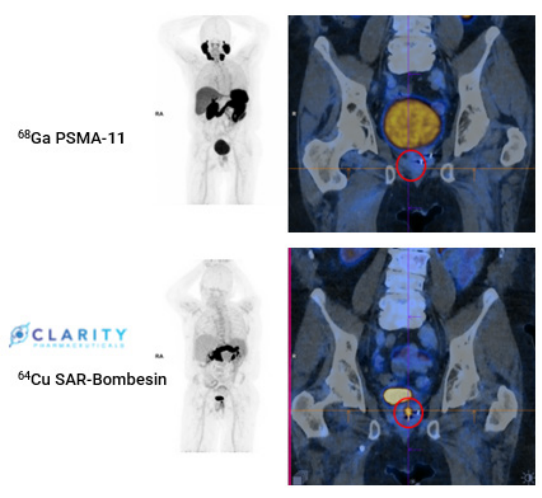
SAR-Bombesin in prostate cancer (PC)

- **75%-100% of PCs express GRPr**
- **~25%** of PC patients **do not express PSMA**
- PSMA-negative PC 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 PC that is PSMA-negative or has a low expression of PSMA

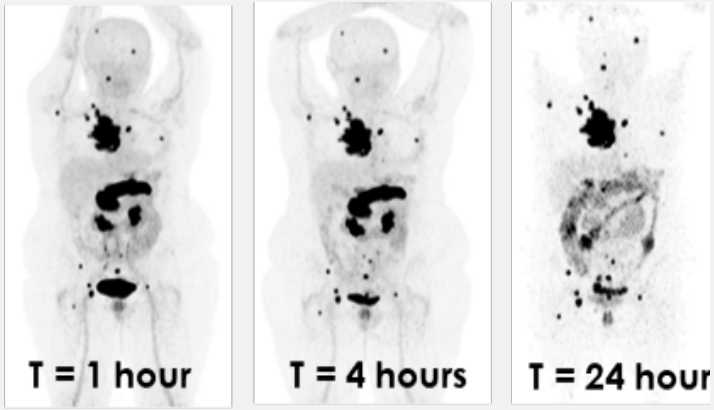
Efficacy of Cu SAR-Bombesin in a mouse model of PC



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

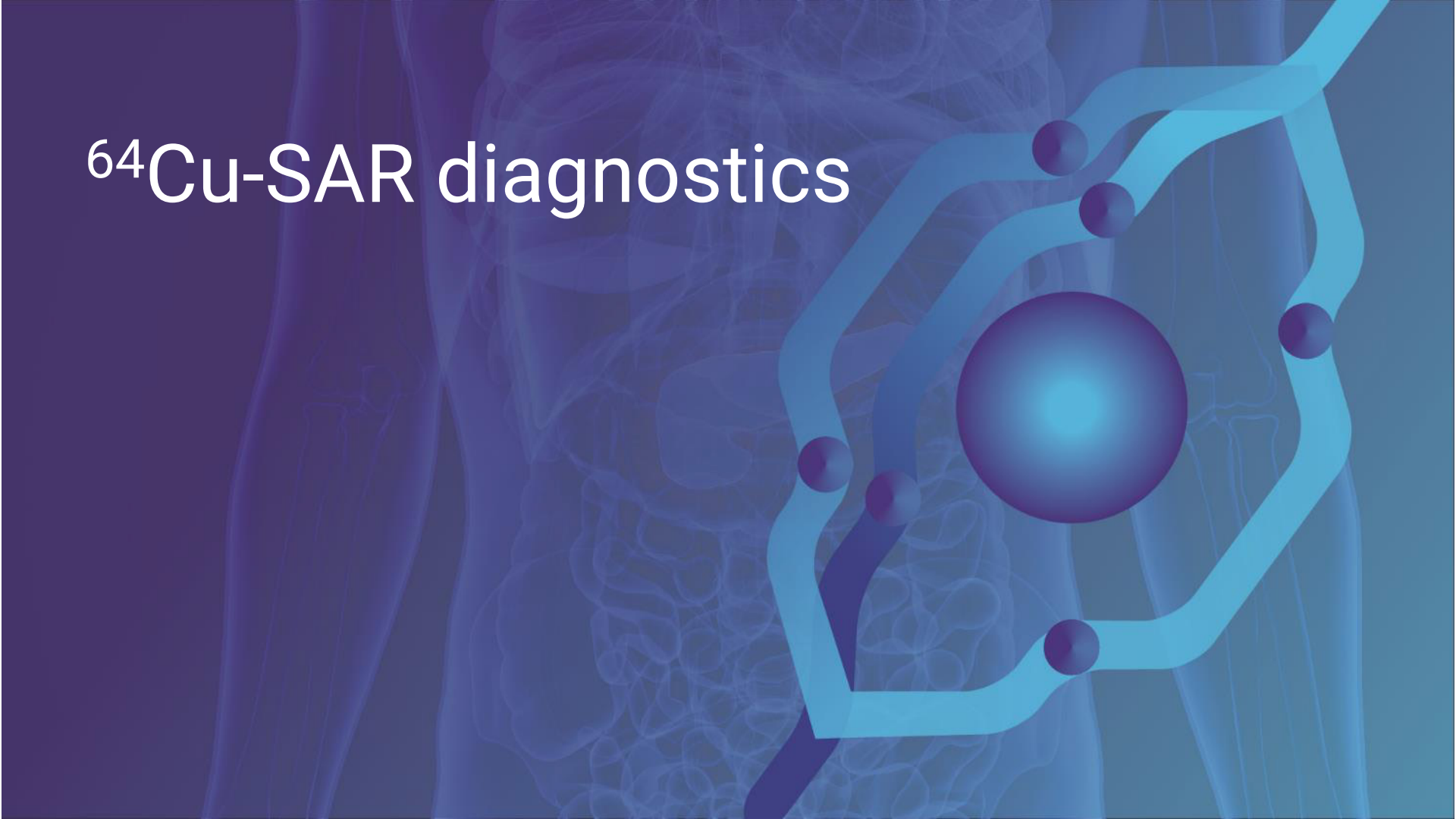


^{68}Ga PSMA-11 (top) images of a PSMA-negative patient with clinical signs of prostate cancer (a rising PSA score of 0.16 ng/mL) and ^{64}Cu SAR-Bombesin PET/CT images of the same patient (bottom)



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

^{64}Cu-SAR diagnostics



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 are set to generate > US$1Bn in 2023.

Lantheus: PYLARIFY® (^{18}F DCFPyL) sales Q2 23: ~US$210M

Telix: Illuccix® (generic PSMA-11 kit) sales Q2 23: ~ US$75M

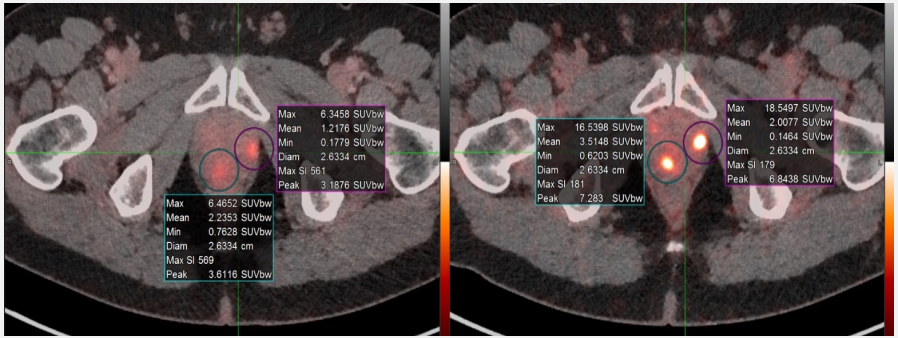
→

Specificity ~ 96% ✓

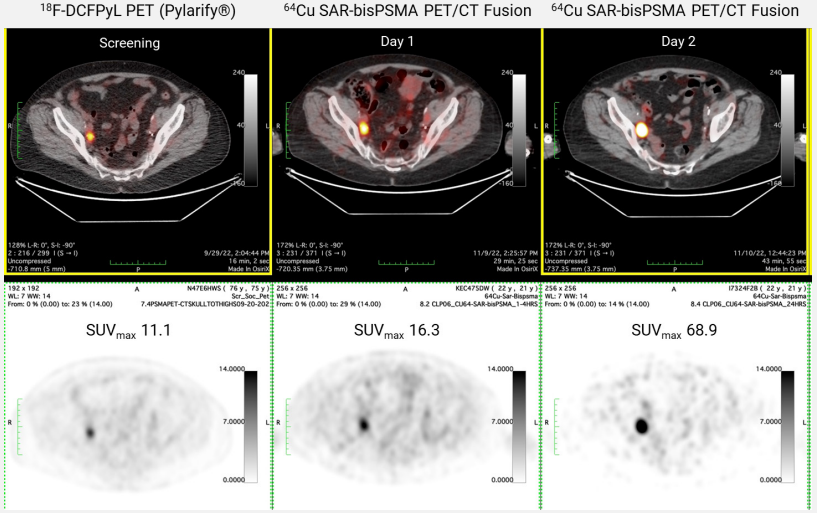
Sensitivity ~ 35% ✗

Comparison with ^{68}Ga PSMA-11 – PROPELLER study

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



Comparison with PYLARIFY® – COBRA study

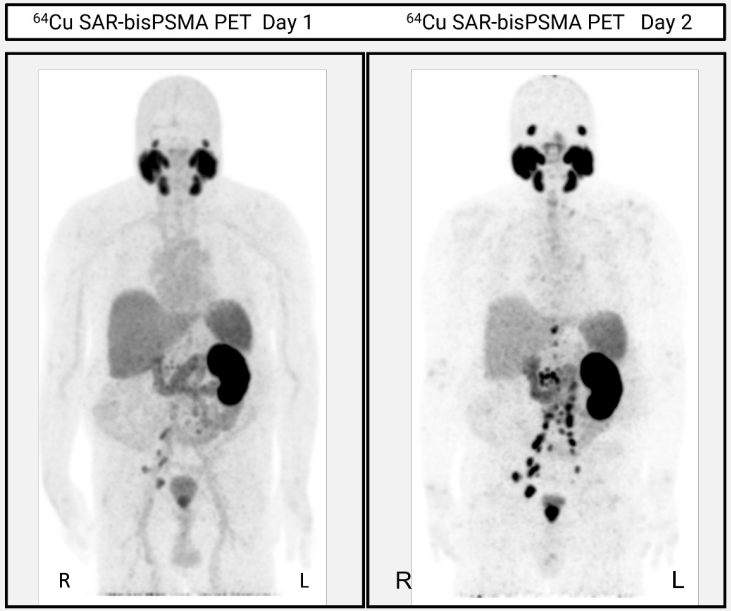


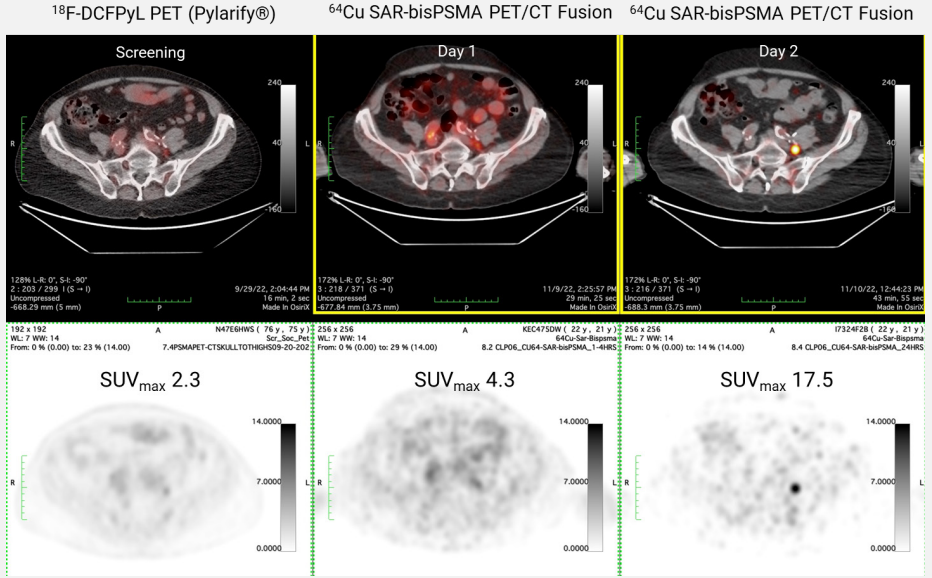
Copper brings significant additional advantages

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

Cu-64 SAR-bisPSMA PET has the ability to image both on the day of administration and at later timepoints, potentially providing clinicians with better insight into the disease

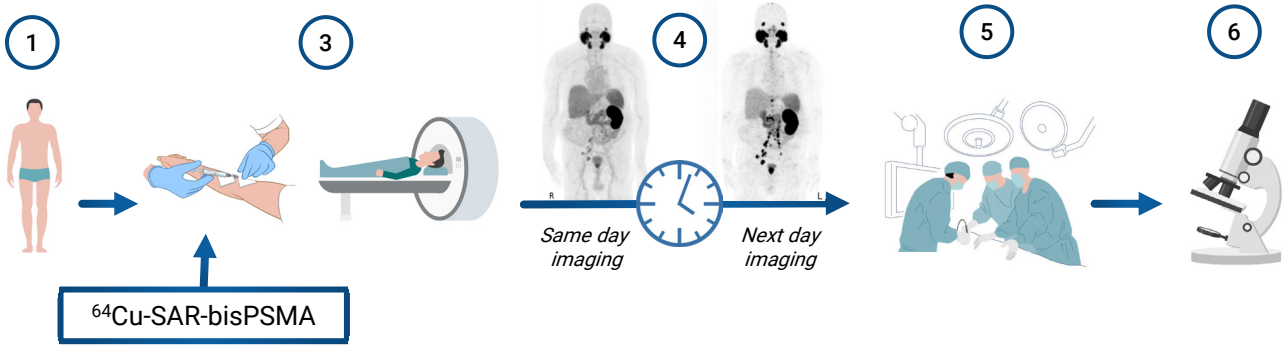
Images from Clarity's COBRA study

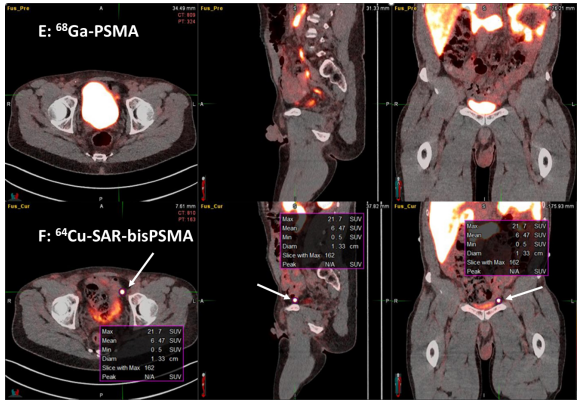




CLARIFY – registrational Phase III trial

CLARIFY is a Phase III diagnostic trial assessing diagnostic performance of ^{64}Cu SAR-bisPSMA in detecting pelvic lymph node metastases of prostate cancer using PET/CT in 383 participants. Recruitment to commence Q4 2023.





PROPELLER trial: 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.

1. Patients with untreated, newly diagnosed prostate cancer who are proceeding to surgery
2. Manufacturing of ^{64}Cu SAR-bisPSMA
3. ^{64}Cu SAR-bisPSMA administration followed by PET/CT scan
4. "Same day" and "next day" imaging (day 1 and day 2)
5. Surgical removal of the prostate and pelvic lymph nodes
6. Histopathology to confirm the results of the PET scan

PET: Positron emission tomography. CT: computed tomography.

SAR-Bombesin

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SAR-Bombesin in PSMA-negative prostate cancer

SABRE

- **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

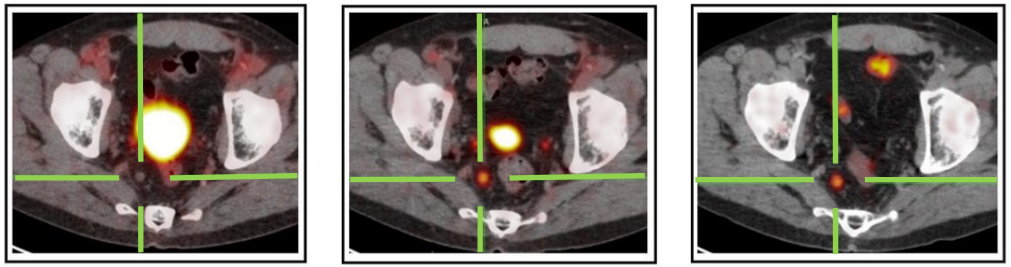
Status

- Recruitment ongoing in the US
- 50% recruitment on 24 July 2023

Next Milestone

- Recruitment complete in Q4 23

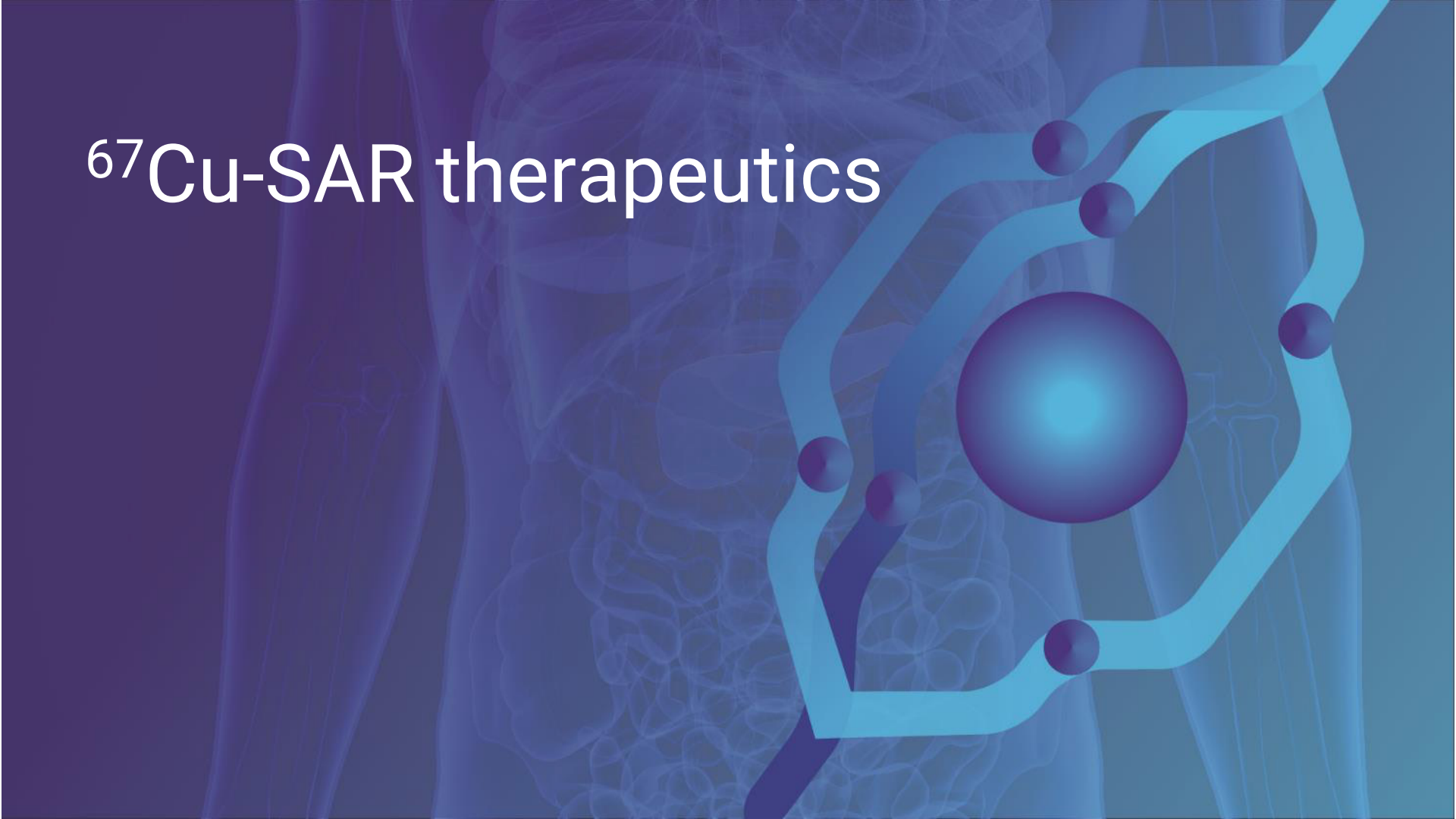
^{18}F-DCFPyl PET/CT (Pylarify®) | ^{64}Cu SAR-BBN PET/CT Day 1 | ^{64}Cu SAR-BBN PET/CT Day 2



Single pelvic lymph node uptake seen on ^{64}Cu SAR-BBN on both Day 1 and Day 2.
A subsequent biopsy has confirmed prostate cancer.

SABRE ClinicalTrials.gov identifier: NCT05407311

^{67}Cu-SAR therapeutics



Metastatic castration-resistant prostate cancer

Clarity is conducting two theranostic clinical trials in mCRPC with two products to treat PSMA-positive, PSMA-negative lesions and those with low PSMA expression

SAR-bisPSMA SECuRE

- Phase I/IIa study of $^{64}Cu/^{67}Cu$ SAR-bisPSMA for identification and treatment of PSMA-expressing mCRPC
- Theranostic multi-centre, single arm, dose escalation study with a cohort expansion planned for up to 44 patients
- 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 the dose expansion phase

Status

- Dosimetry phase with ^{64}Cu SAR-bisPSMA in mCRPC completed
- Dose escalation phase underway
- Cohort 1 completed with no safety issues (4GBq dose level)
- Cohort 2 completed with no safety issues (8GBq dose level)
- Cohort 3 recruiting (1st patients dosed at 12GBq dose level)

Next milestone

- Cohort 4 open for recruitment

SAR-Bombesin COMBAT

- A Phase I/IIa theranostic study of ^{64}Cu SAR-Bombesin and ^{67}Cu SAR-Bombesin for identification and treatment of GRPR-expressing mCRPC in patients who are ineligible for therapy with ^{177}Lu-PSMA-617
- Theranostic, multi-centre, single arm, dose escalation/dose expansion study with a cohort expansion planned for up to 38 patients

Status

- Open for recruitment

Next milestone

- Cohort 2 open for recruitment

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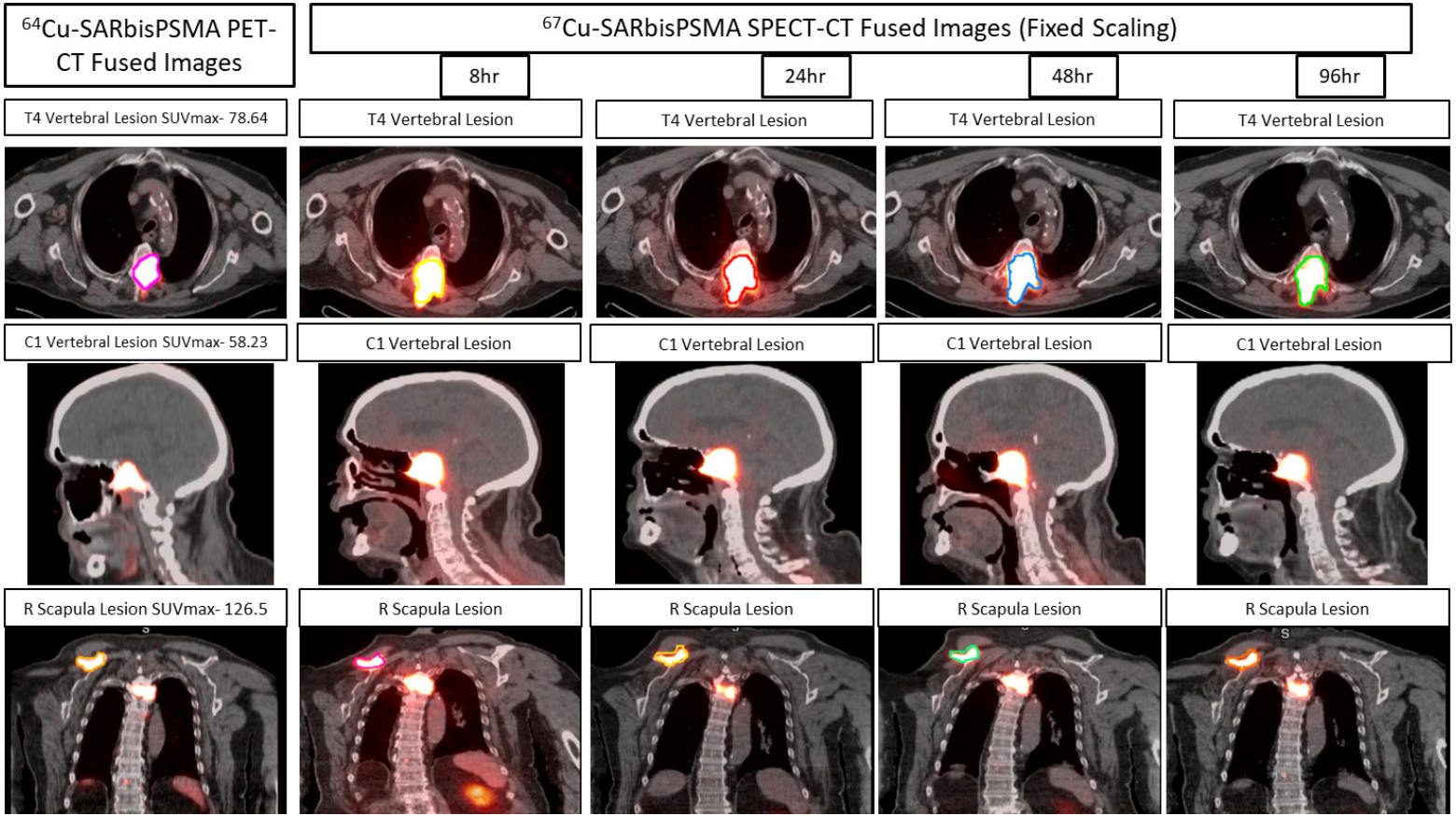
SECuRE clinicaltrials.gov identifier: NCT04868604

COMBAT ClinicalTrials.gov identifier: NCT05633160

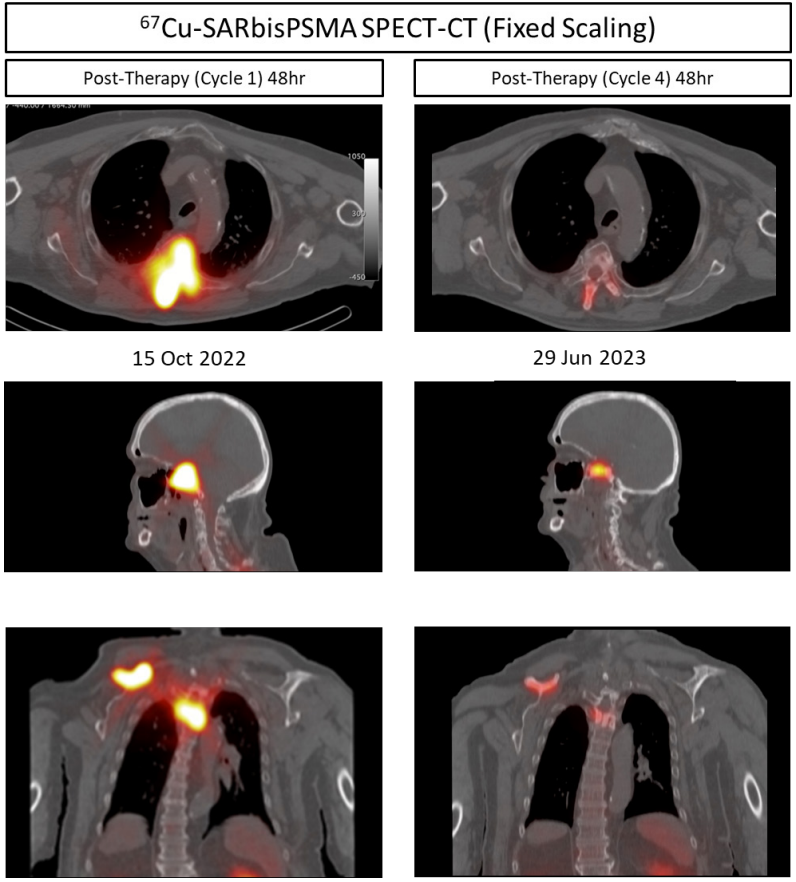
SECuRE cohort 1 - 4GBq dose level



US FDA Expanded Access Program

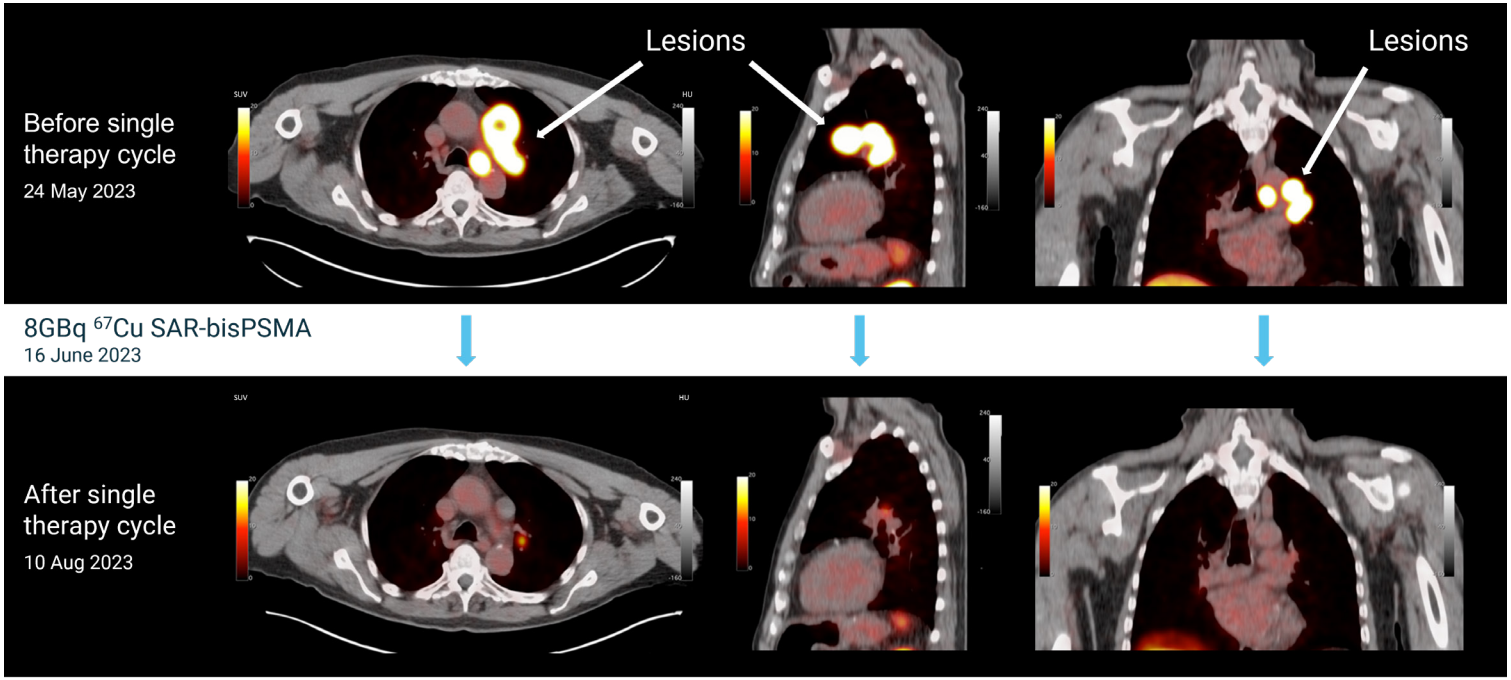
- Additional therapy cycles of ^{67}Cu SAR-bisPSMA at the lowest 4GBq dose level have been requested under the US FDA Expanded Access Program (EAP)
- Early data indicates positive effects
- SPECT-CT images (on the right) demonstrate a reduction in the intensity of product uptake at the tumour sites after four doses, signaling tumour shrinkage
- Same patient experienced a reduction in PSA levels >50% following the first dose, and a >90% decline in PSA after dose 4

4GBq ^{67}Cu SAR-bisPSMA over 4 cycles



SECuRE cohort 2 - 8GBq dose level (single cycle)

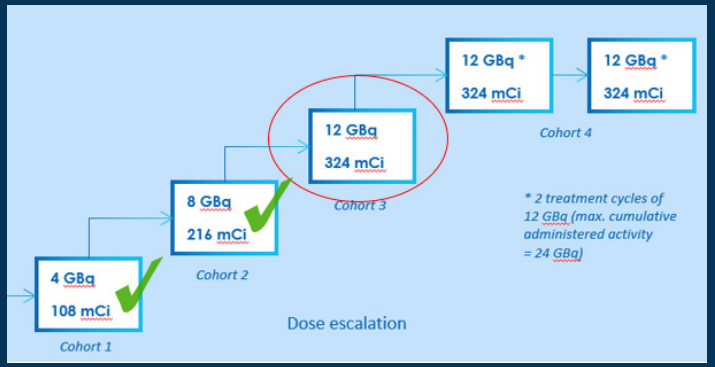
- No Dose Limiting Toxicities with single cycle at 8GBq
- All 3 participants had a PSA drop of > 70%
- Significant reduction in uptake of the diagnostic dose after a single 8GBq therapy cycle



^{64}Cu SAR-bisPSMA PET/CT imaging before and after a single cycle of 8GBq ^{67}Cu SAR-bisPSMA (cohort 2)

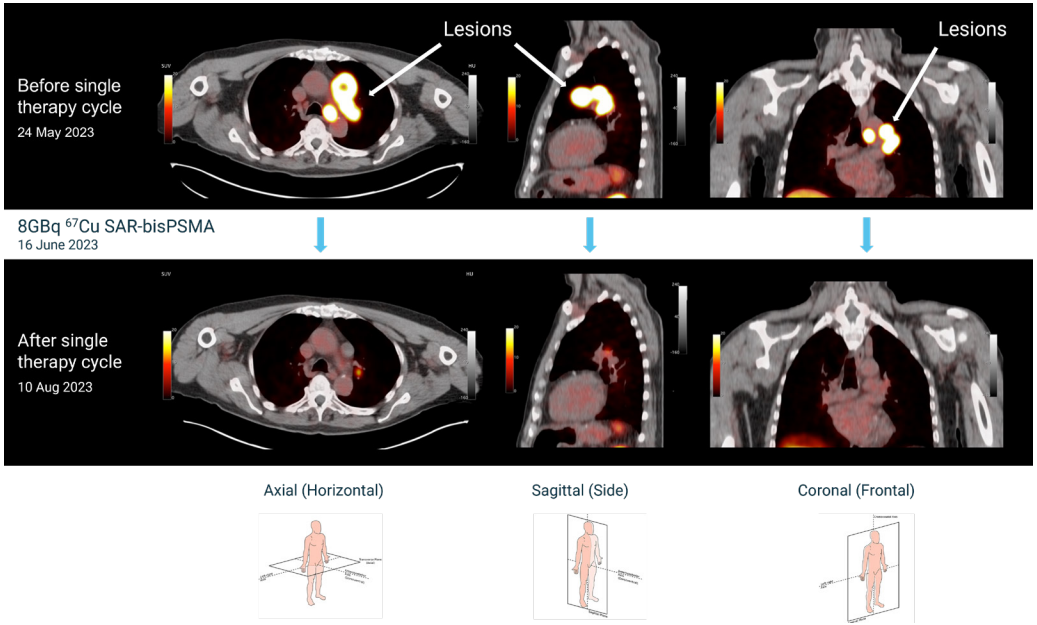
^{67}Cu SAR-bisPSMA in mCRPC: Now in cohort 3

- No Dose Limiting toxicities with single cycles at 8GBq
- All 3 participants had a PSA drop of > 70%
- Additional 8GBq doses requested under FDA EAP
- Now administering 12GBq doses in cohort 3 (6 patient cohort)



SECuRE

^{64}Cu SAR-bisPSMA PET/CT imaging before and after a single cycle of 8GBq ^{67}Cu SAR-bisPSMA (cohort 2)



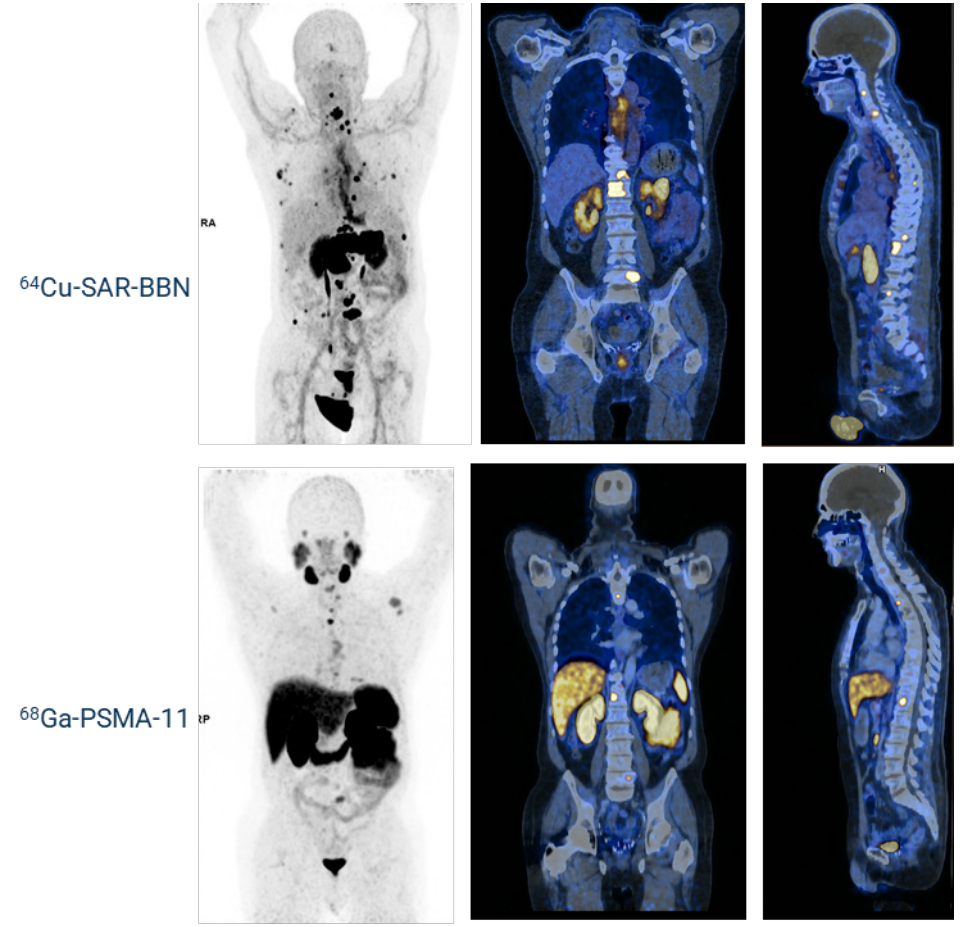
CLARITY PHARMACEUTICALS

^{67}Cu SAR-Bombesin in mCRPC

Benefits

- ^{67}Cu SAR-Bombesin could be used in combination with PSMA-based therapies to ensure both PSMA- and GRPr-positive tumours are treated, or as a stand-alone therapy in PSMA-negative PC

^{64}Cu SAR-Bombesin and ^{68}Ga PSMA-11 PET and PET/CT images in a participant in the BOP IIT (mCRPC cohort) conducted by Prof Emmett at St Vincent's hospital in Sydney, Australia



CLARITY PHARMACEUTICALS

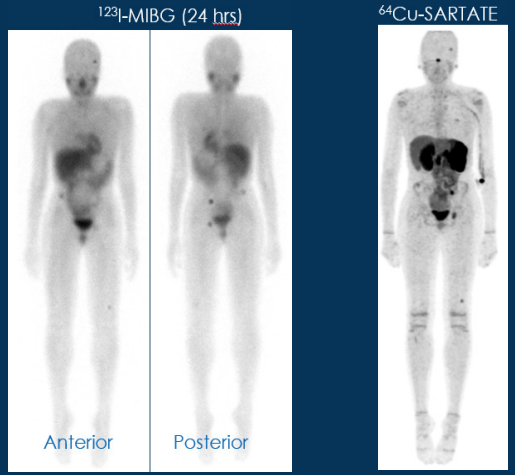
Neuroblastoma therapy with ^{67}Cu SARTATE

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)

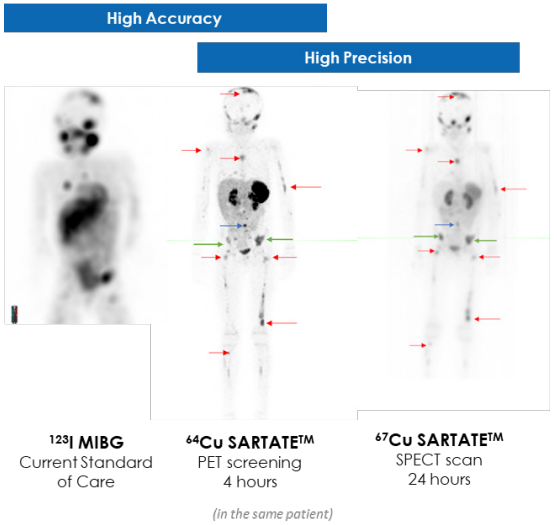
24 Jan 2023

CL04

CL04 trial is a ^{67}Cu-SARTATE peptide receptor radionuclide therapy administered to paediatric patients with high-risk, relapsed, refractory neuroblastoma

Status

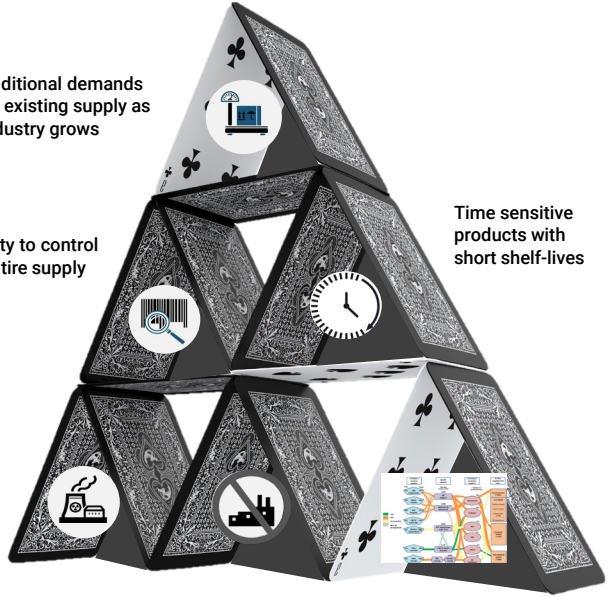
- Cohort 1 complete, no safety issues (3 patients) 75MBq/kg b.w.
- Cohort 2 complete, no safety issues (3 patients) 175MBq/kg b.w.
- Cohort 3 complete, no safety issues (3 patients) 275MBq/kg b.w.
- **Cohort 4 recruiting (6 patients) 375MBq/kg b.w**
- Recruiting at multiple sites in the US



CL04 ClinicalTrials.gov identifier: NCT04023331

The Supply Differentiator

Current industry challenges



Combined with a history of supply issues

nature › news › article

Published: 12 September 2016

Reactor shutdown threatens world's medical-isotope supply

SNMMI SOCIETY OF NUCLEAR MEDICINE AND MOLECULAR IMAGING

August 6, 2018

US Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Shortage of Germanium-68/Gallium-68 Generators for the Production of Gallium-68

NewScientist

SUBSCRIBE AND SAVE 60%

Australia has a huge shortage of the medical isotope needed for scans

21 September 2019

MANUFACTURING

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

By Angus Liu • May 5, 2022 12:44pm

wnn world nuclear news
Celebrating 15 years

Energy & Environment | New Nuclear | Regulation & Safety | Nuclear Policies | Corporate | Uranium & Fu

Medical isotope supply chain faces challenges from COVID-19

21 April 2020

Bayer Suspends Production of Radium-223 Due to Manufacturing Problem

October 17, 2014
Beth Fand Incollingo

Create challenges for prescribers

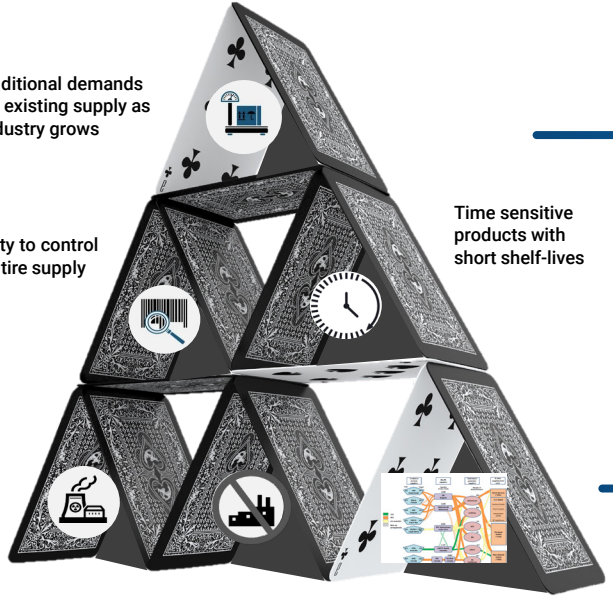
Oncologists need a safe, dependable and reliable source of radiopharmaceutical products

"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

CLARITY PHARMACEUTICALS

Current industry challenges



Additional demands on existing supply as industry grows

Inability to control the entire supply chain

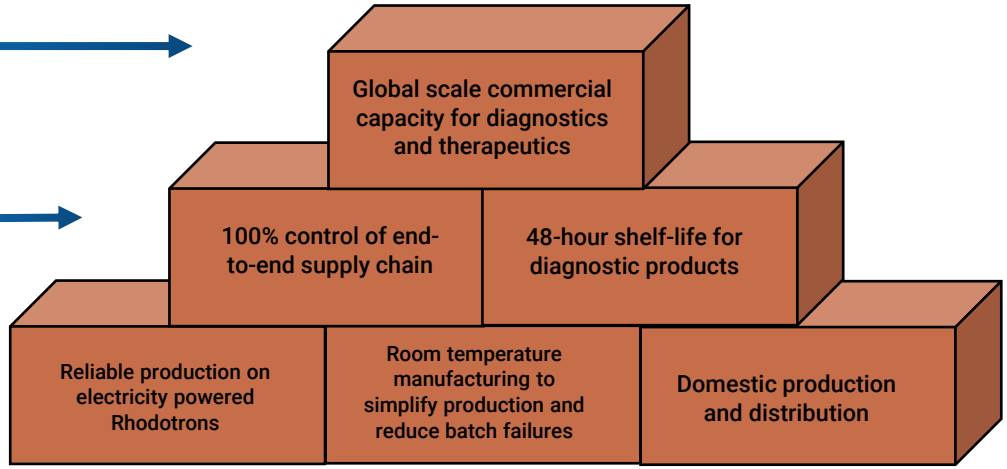
Time sensitive products with short shelf-lives

Reliance on ageing nuclear reactor fleet

Manufacturing outages

Complex international supply chains

Clarity's TCTs Solution



MANUFACTURING

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

By **Angus Liu** · May 5, 2022 12:44pm

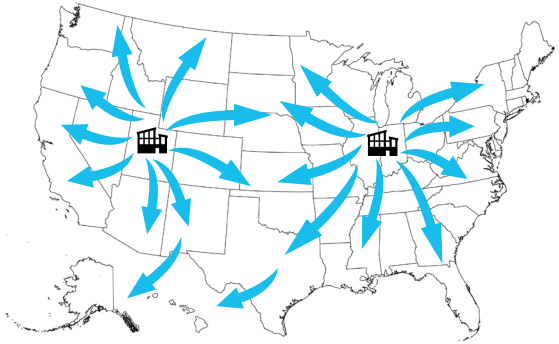
"We have patients on months long waiting lists when this may be all the time they have, and so it's been really disheartening to have to deal with these things"

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

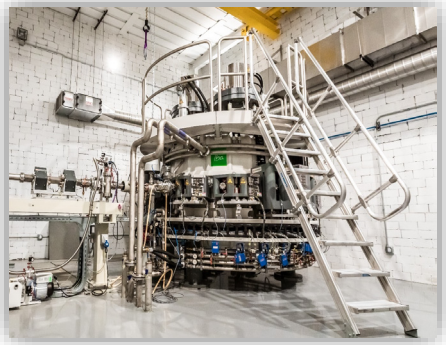
Next-generation theranostics provide solutions to the challenges with current-generation radiopharmaceuticals

Opportunities with ^{64}Cu (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 ^{18}F products
- Ability to centralise investments and supply the country
- Delivered as a ready-to-use cGMP product



Opportunities with Rhodotron produced ^{67}Cu



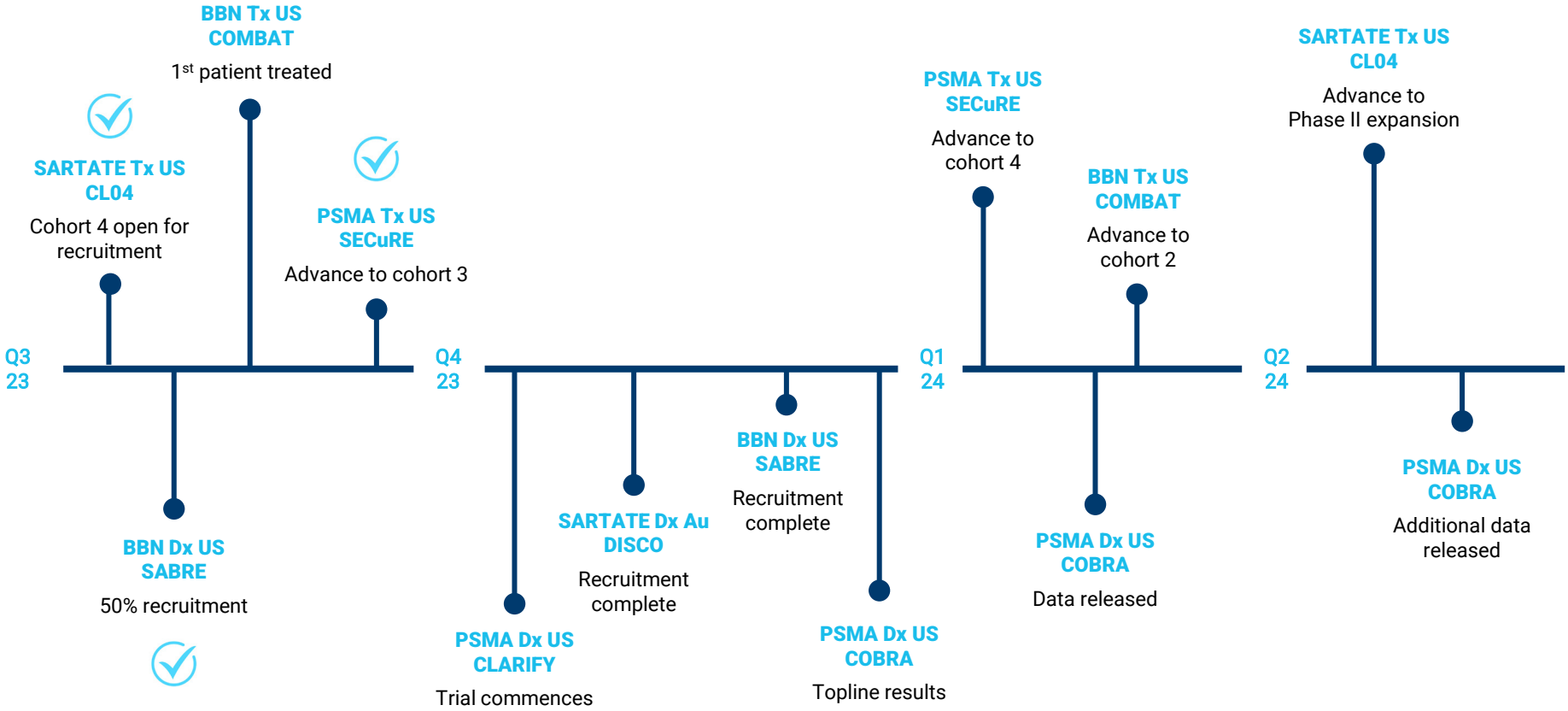
- Commercially available high powered rhodotron with a small footprint (10' diameter and 11' tall)
- Scalable with relatively small investments
- Purpose-built supply in the markets of focus, including a US domestic supply
- Only inputs are electricity and Zinc
- No long-lived impurities
- Exclusive supply agreement with NorthStar Medical Isotopes
- **A single rhodotron can produce commercial quantities of ^{67}Cu**

"Access to reactors will soon become the bottleneck for ^{177}Lu"[1]

1. https://jnm.snmjournals.org/content/jnumed/early/2023/08/17/jnumed.123.265907.full.pdf

Key upcoming milestones

Dx = Diagnostics
Tx = Theranostics



Summary

Global leader in Targeted Copper Theranostics (TCTs)

- **Extensive pipeline** of TCTs based on ^{64}Cu for diagnosis and ^{67}Cu for therapy
- Multiple therapeutic and diagnostic trials in progress 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 **~$65million** 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
- **Highly active M&A sector** with numerous recent acquisitions

Thank you

Contact details

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Managing Director and CEO
E: colin.biggin@claritypharm.com