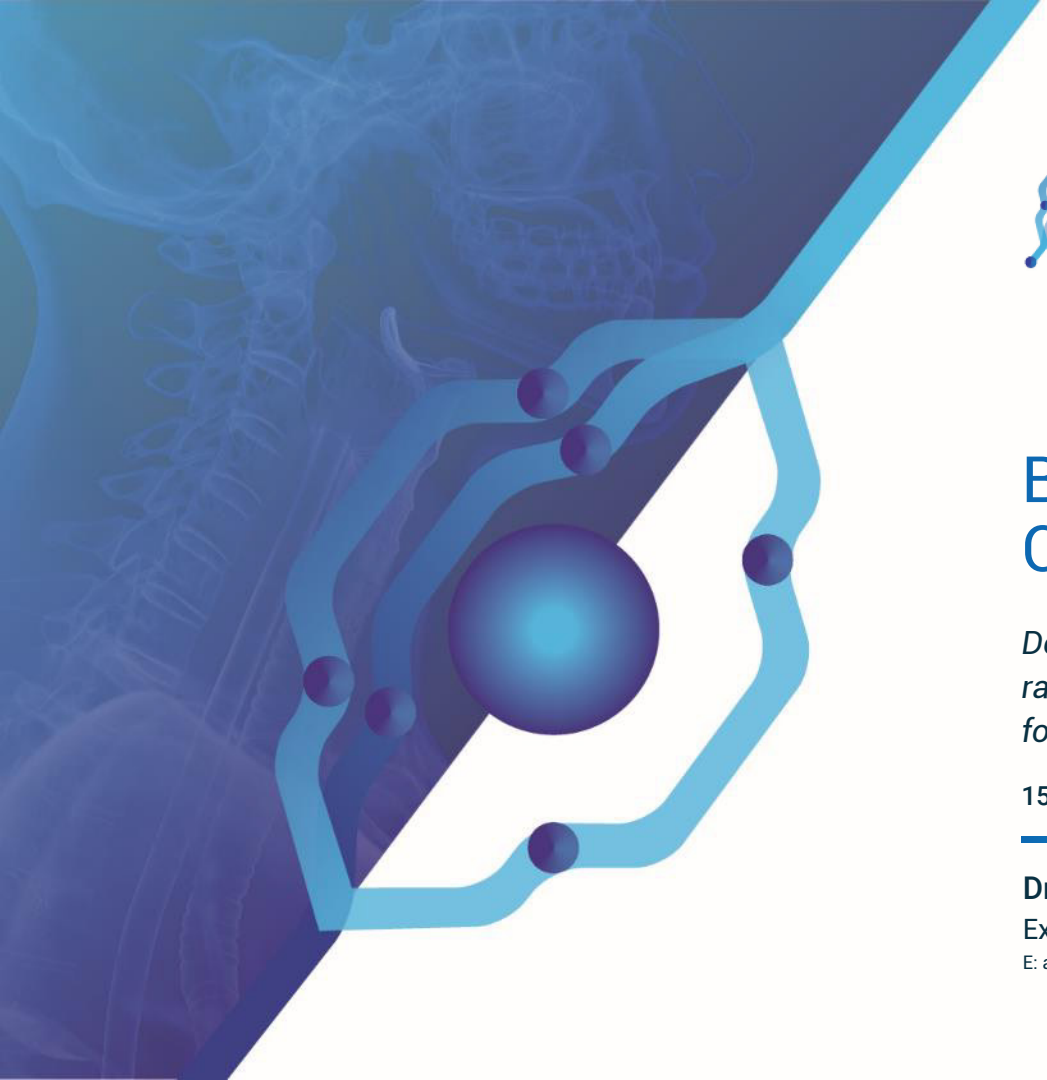

CLARITY
PHARMACEUTICALS

Bell Potter Healthcare Conference

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

15th November 2023

Dr Alan Taylor
Executive Chairperson
E: alan.taylor@claritypharm.com

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Corporate Snapshot

Proprietary SAR Technology: a true platform technology

Three best-in-class products in clinical development protected by 24 patent families, 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

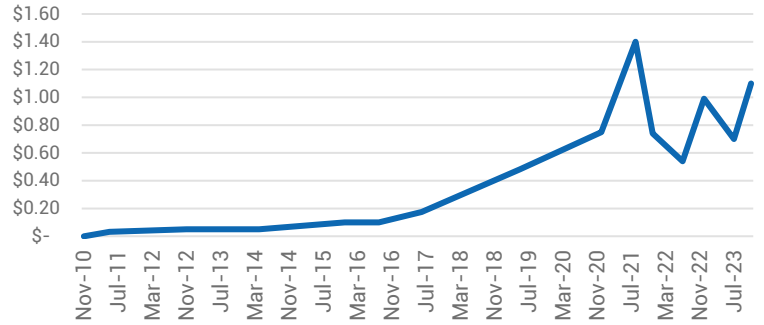
Diverse and in-depth expertise spanning corporate finance, operations, commercialisation & industry. Significant radiopharmaceutical experience across all functions

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[1]	A$1.10
Cash at bank[2]	A$53.6M
Shares on issue	261.9M
Options on issue	26.2M
Market cap (undiluted)[2]	A$288.1M

1. As at 10 November 2023
2. As at 30 September 2023

Share price

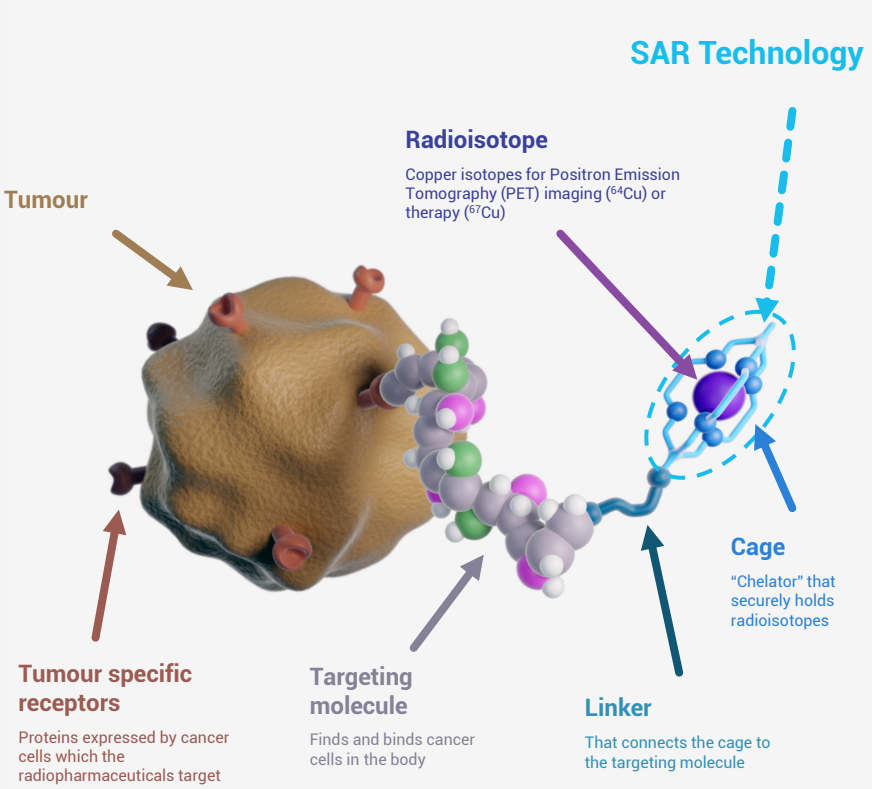


Clarity – The Copper Theranostics Company

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

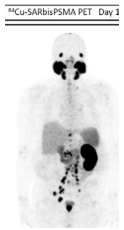


Why Copper?

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

Diagnostic radionuclides

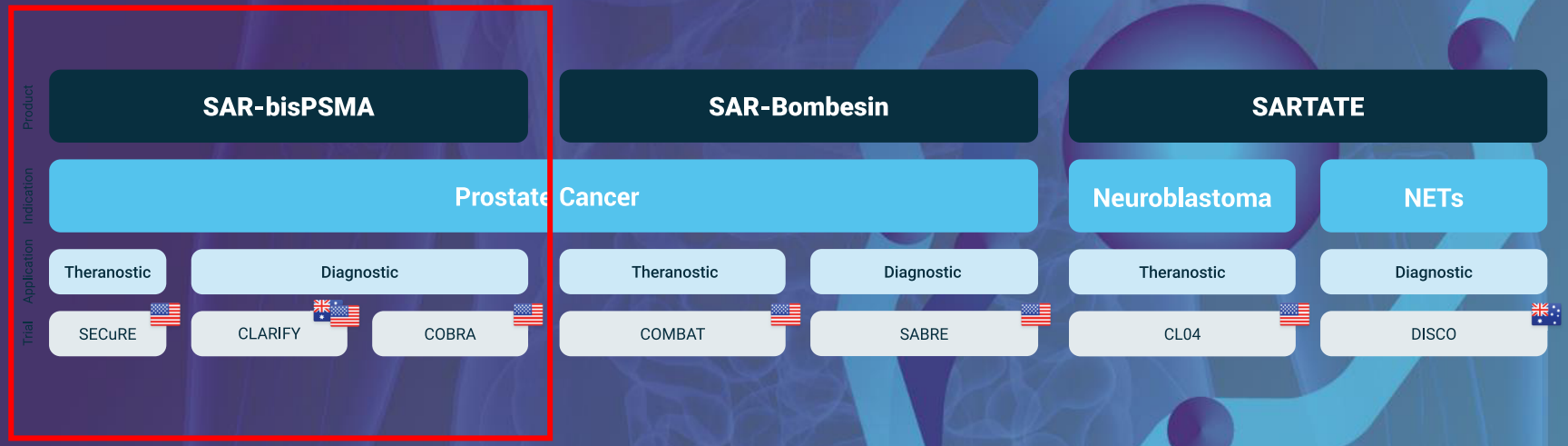
	Copper-64	Gallium-68	Fluorine-18
Half life	12.7 hours	1.1 hours	1.83 hours
Typical product shelf life	Up to 48 hours	Up to 4 hours	Up to 10 hours
Production	Cyclotron	Mainly from Generators	Cyclotron
Imaging window	From 1 to >48 hours	~60 mins	~60 mins
Ability to centrally manufacture	Yes	No	No



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)

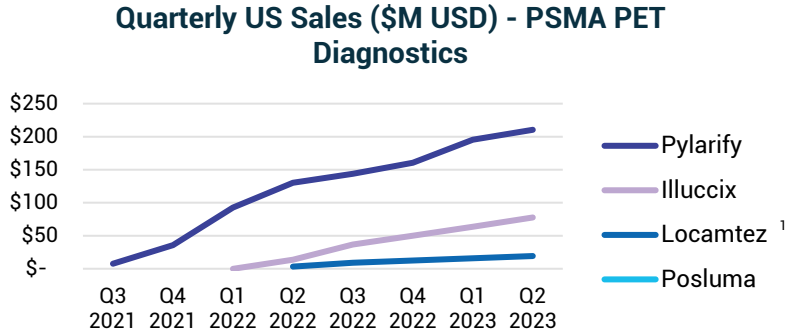
Three key product areas



SAR-bisPSMA market opportunity

PSMA based diagnostics

- Current US patient pool for PSMA-PET imaging is **~355k scans per year** between initial-staging, suspected recurrence and patient selection for targeted therapy
- At ~US$4.4k per patient dose this represents a US market potential of **~US$1.55Bn/year**
- By 2028 this is expected to grow to 600,000 scans per year, representing a US market potential of **>US$3Bn/year**



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

PSMA based therapy (mCRPC)

- Current US market opportunity (post chemo): **>US$5Bn**
- Future US market opportunity (including pre-chemo): **>US$10Bn**
- Novartis YTD CY23 Pluvicto sales were ~US$707M despite the significant supply challenges

[1]Locametz sales estimated at 25% of Illuccix sales

Clarity's three areas of focus in prostate cancer

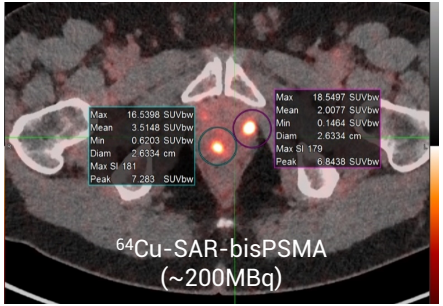
Prostate cancer is the second largest oncology indication in men; there are three stages of prostate cancer

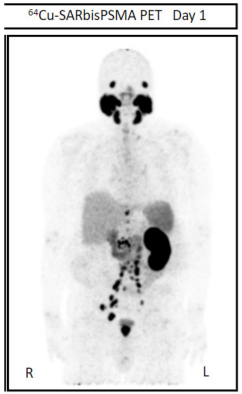
Primary → Biochemical recurrence (BCR) → Metastatic castration-resistant (mCRPC)

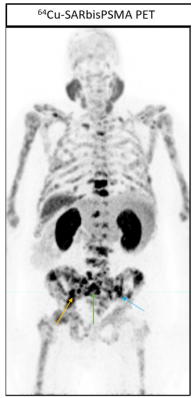
- PC localised in the prostate gland with a main (primary) tumour
- Unless the disease has spread, the most common treatment is a surgery called prostatectomy (removal of the prostate) or radiation therapy

- 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





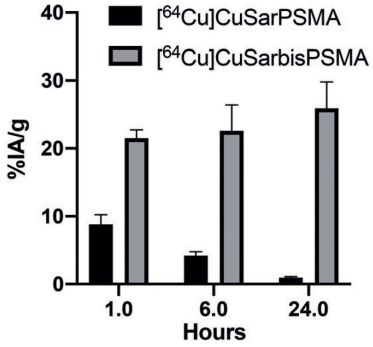


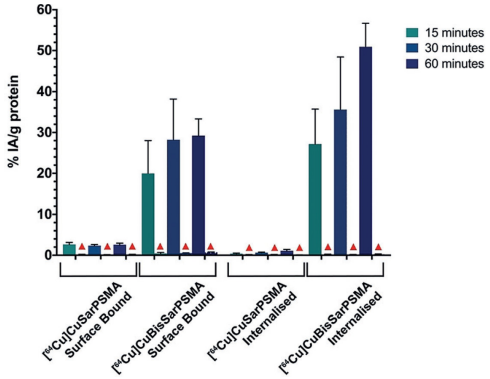
64Cu-SAR-Diagnostics

67Cu-SAR-Therapy

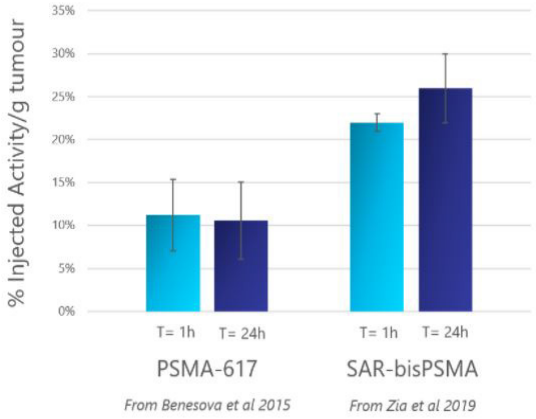
SAR-bisPSMA

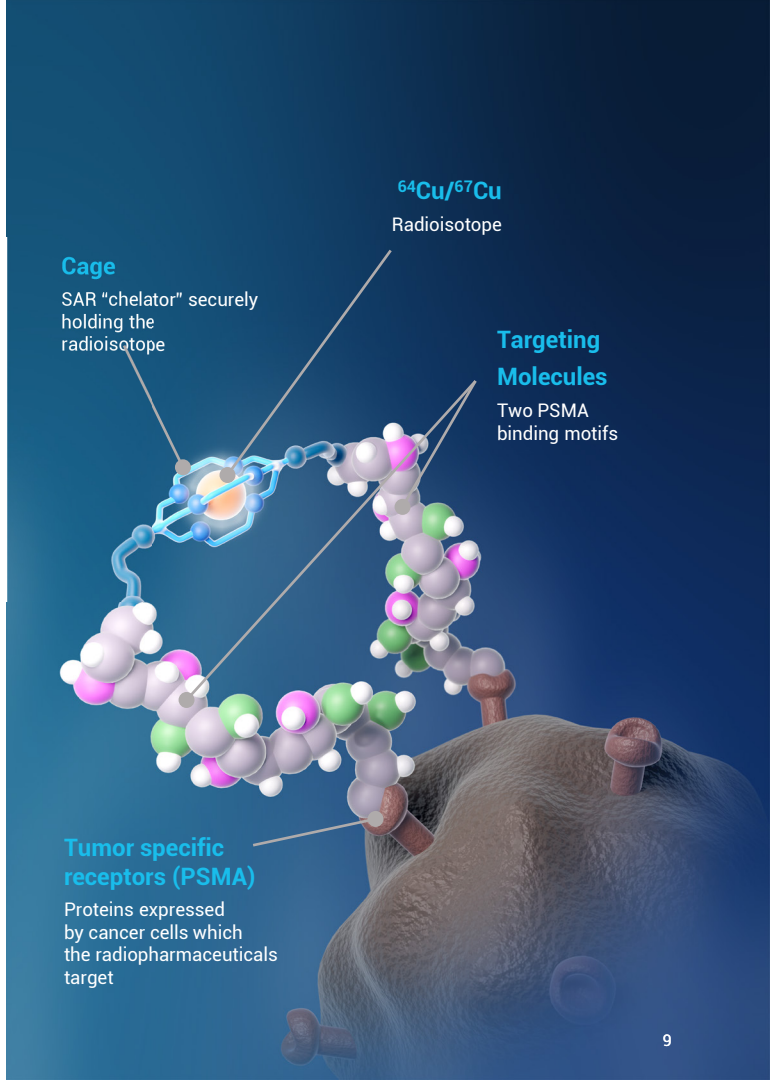
Superior performance of bisPSMA compared to monomer PSMA





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





Zia et al., 2019. Ang.Chem

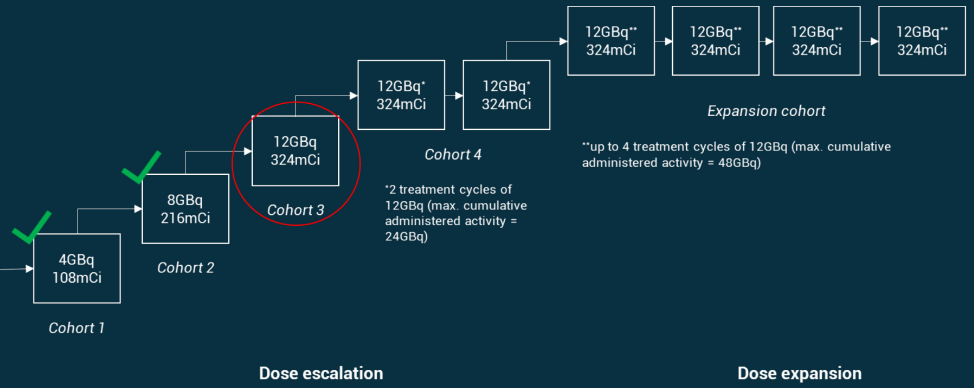
^{67}Cu-SAR therapeutics

Therapy program with ^{67}Cu-SAR-bisPSMA

Currently recruiting into cohort 3 in the US-based study

Trial overview

- Phase I/II study in mCRPC
- Participants do not need to have received chemotherapy
- Dose escalation followed by cohort expansion with up to 4 cycles of therapy

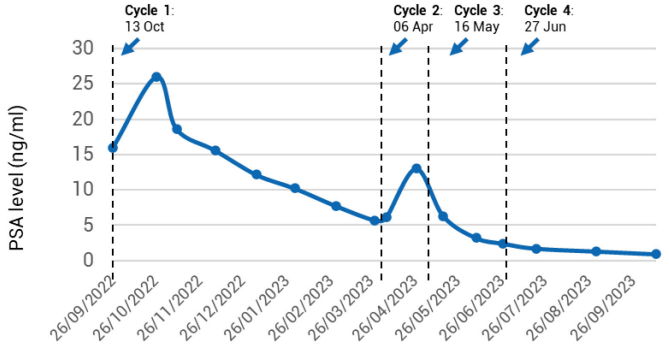


SECuRE

Trial highlights to date

- Now recruiting in cohort 3 at 12GBq dosing (Pluvicto dose capped at 7.4GBq)
- Third of patients in cohort 1 had a PSA decline greater than 50% from a single cycle
- 100% of patients in cohort 2 had a PSA decline greater than 80% from a single cycle
- No DLTs have been observed to date
- Additional therapy cycles have been administered in cohorts 1 and 2 under FDA EAP

PSA reduction following 4 doses of 4GBq of ^{67}Cu-SAR-bisPSMA



Dash lines: administration of ^{67}Cu-SAR-bisPSMA

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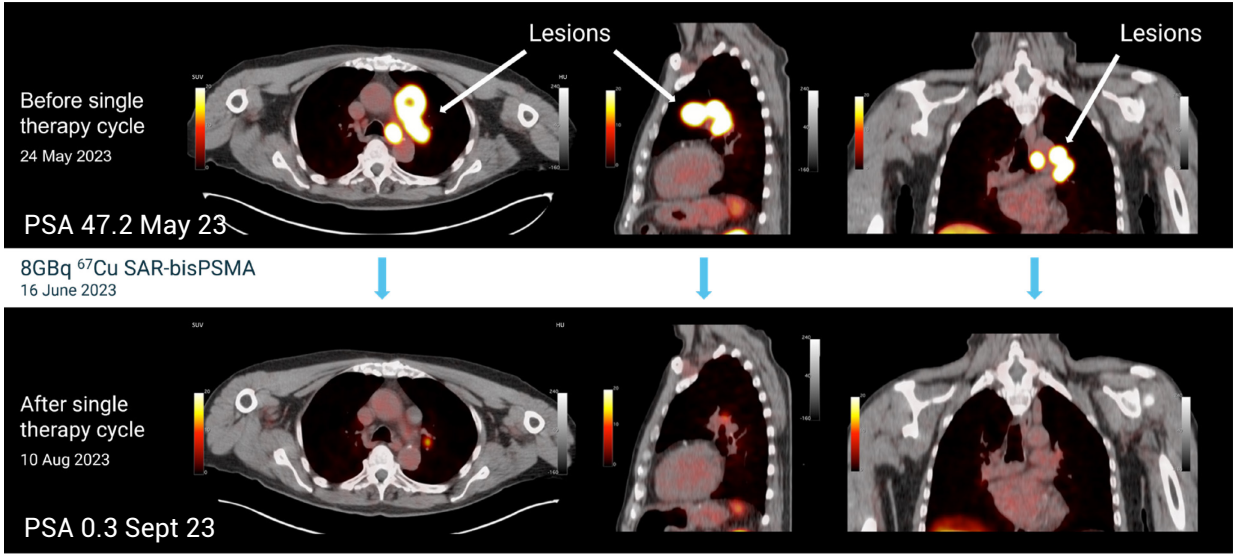
^{67}Cu-SAR-bisPSMA therapy
Phase I/II SECURE trial in mCRPC :

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



Cohort 2 (n=3)	PSA decrease following single therapy cycle
1	>95%
2	>99%
3	>80%

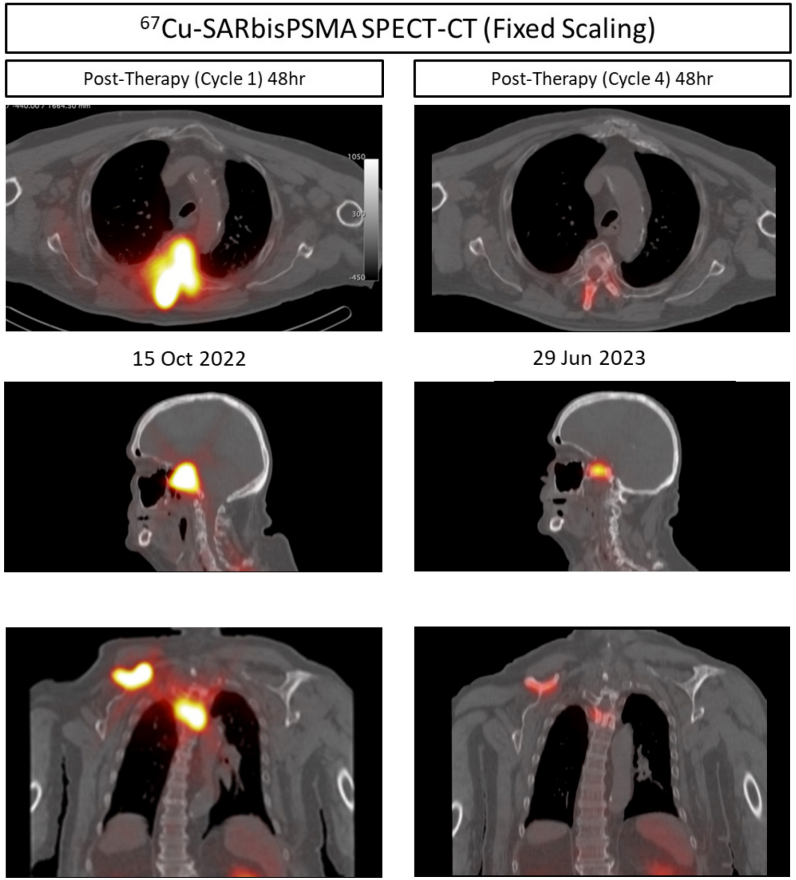
Considerable reduction in uptake of ^{64}Cu-SAR-bisPSMA on imaging following administration of ^{67}Cu-SAR-bisPSMA

Next updates
- Dosing of first three patients in cohort 3 (12GBq) completed; Safety Review Committee meeting planned for end of November
- Second group of three patients in cohort 3 expected to be recruited this year
- Cohort 4 expected to commence recruitment in Q1 24

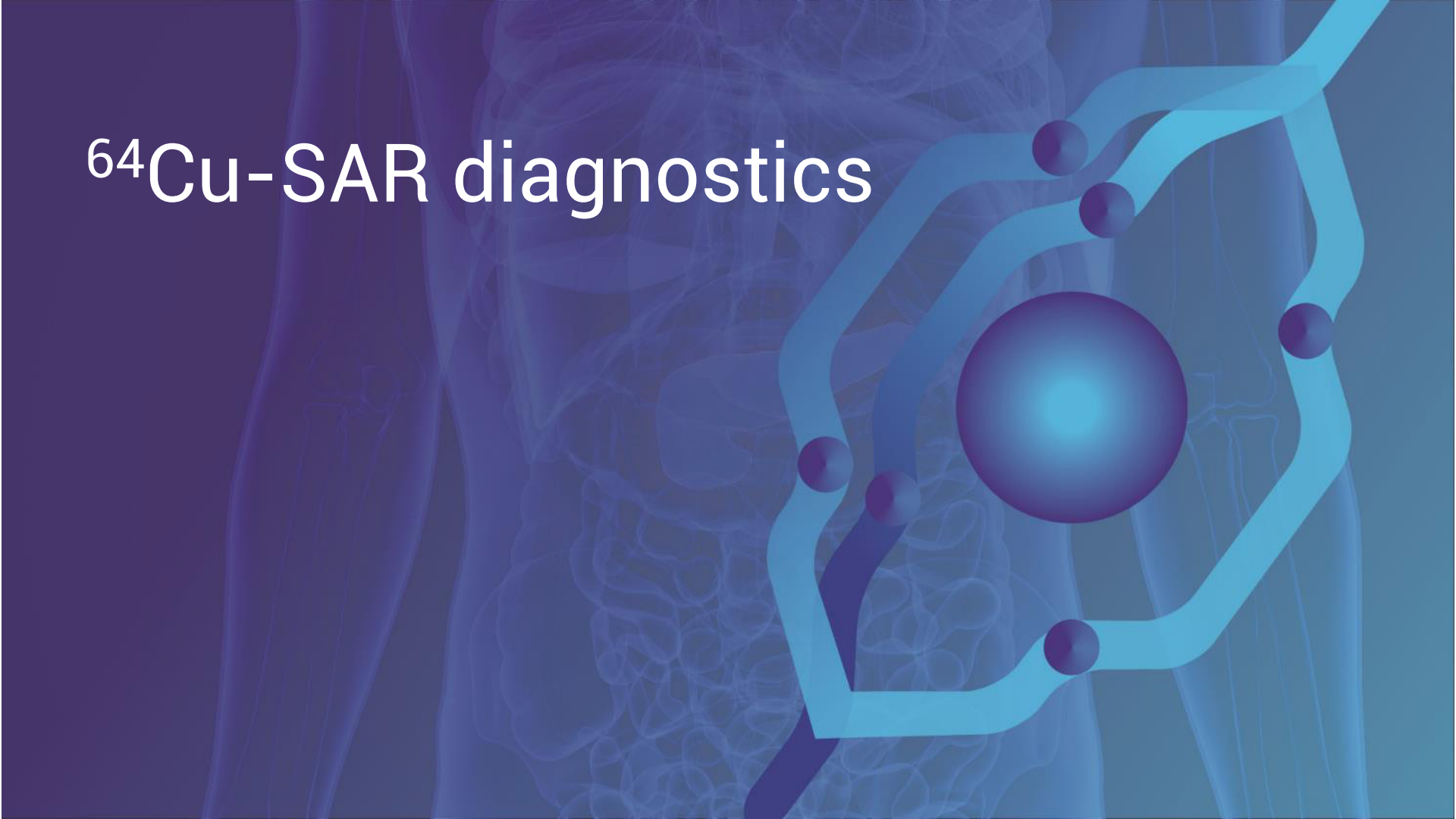
US FDA Expanded Access Program

- 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



^{64}Cu-SAR diagnostics

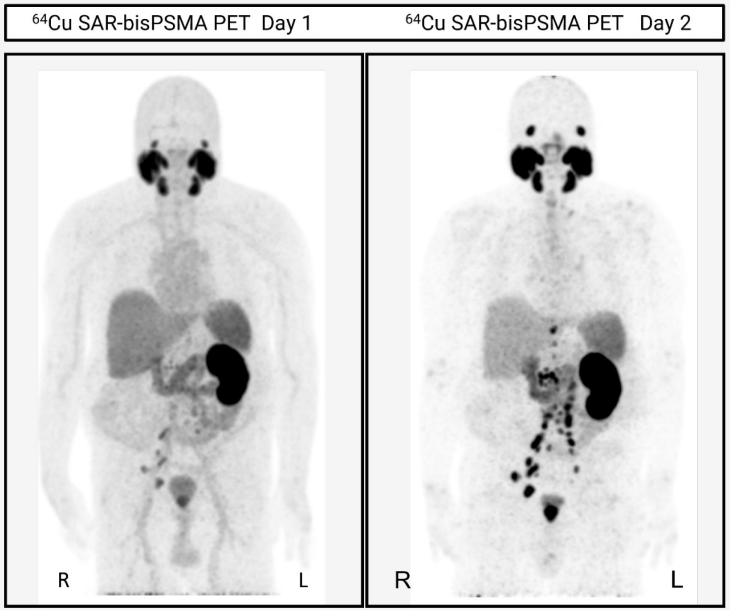


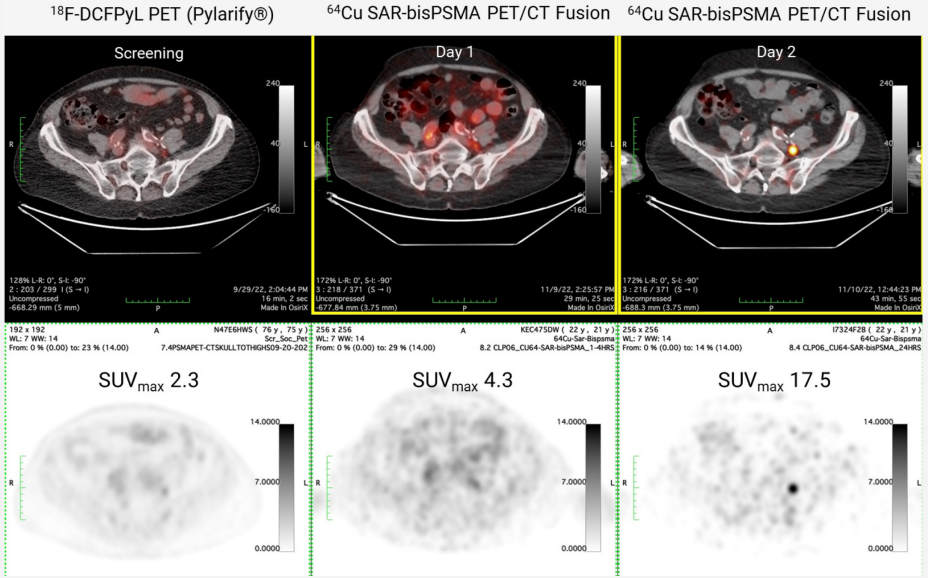
Copper brings significant additional advantages

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

^{64}Cu-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





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 Q3 23: ~US$215M

Telix: Illuccix ® (generic PSMA-11 kit) sales Q3 23: ~ US$85M

→

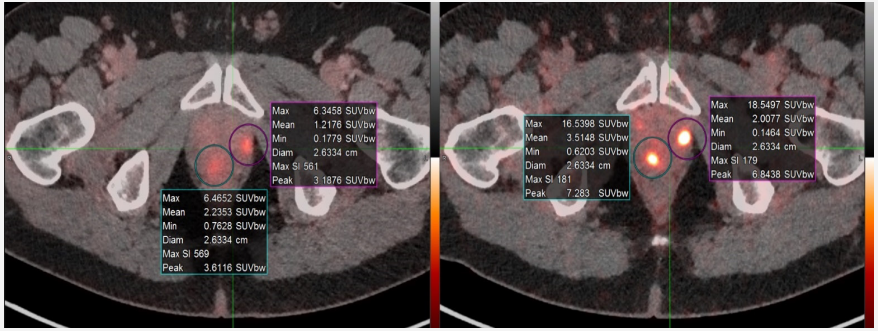
Specificity ~ 96% ✓

Sensitivity ~ 35% ✗

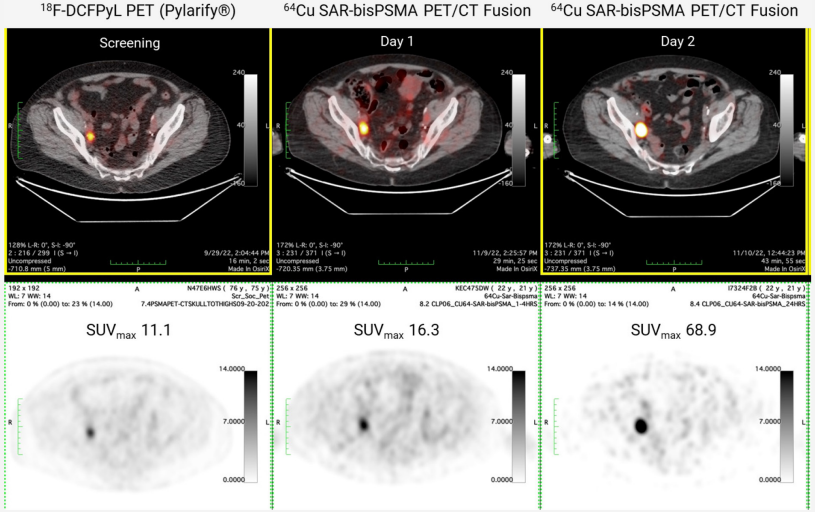
Comparison with ^{68}Ga-PSMA-11 – PROPELLER study

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

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

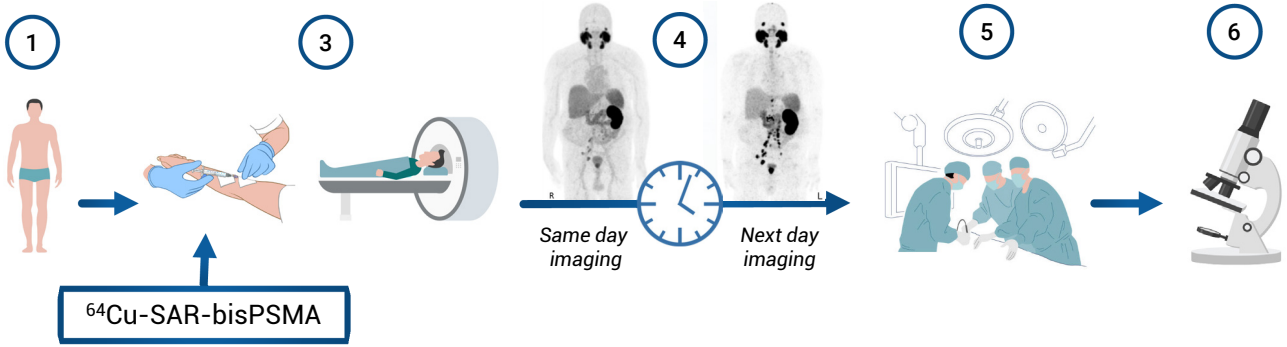


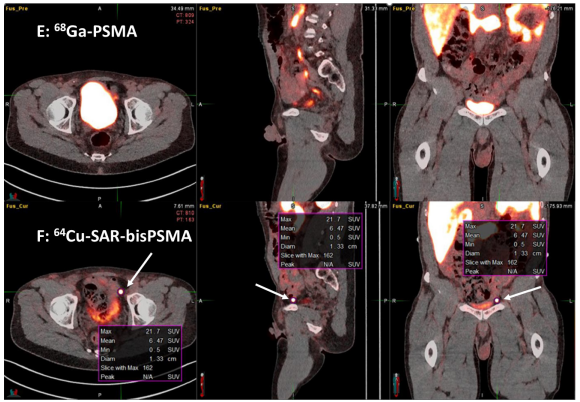
Comparison with PYLARIFY® – COBRA study



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.

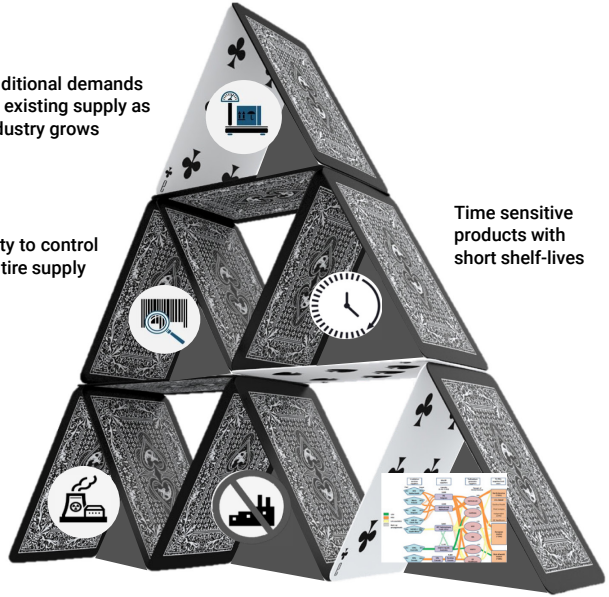
CLARIFY

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.

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

SNMI 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

MANUFACTURING

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

By Angus Liu • May 5, 2022 12:44pm

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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

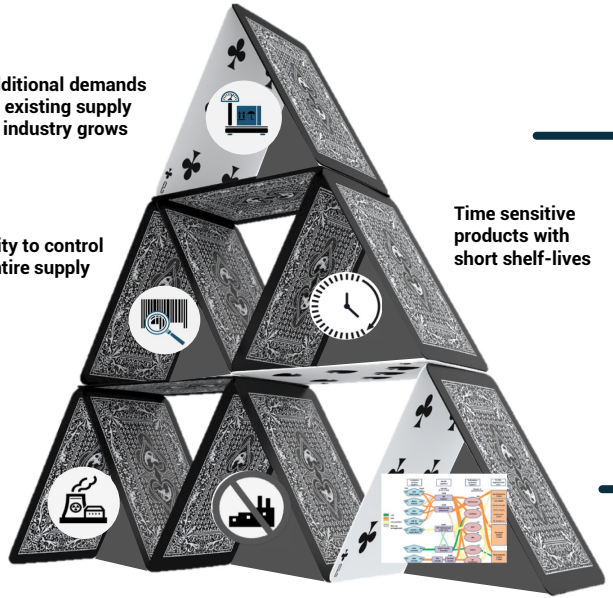
Create challenges for prescribers

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

Current industry challenges with ^{68}Ga & ^{177}Lu



Additional demands on existing supply as industry grows

Inability to control the entire supply chain

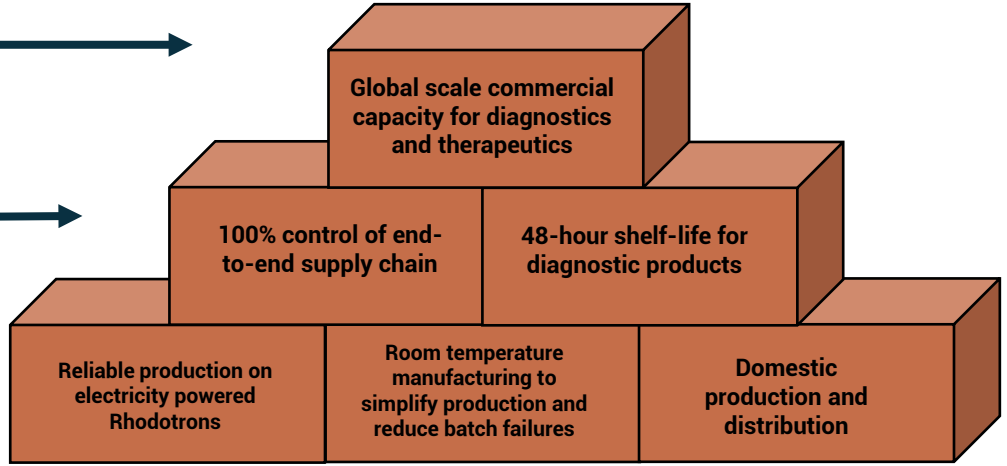
Time sensitive products with short shelf-lives

Reliance on ageing nuclear reactor fleet

Manufacturing outages

Complex international supply chains

Clarity's TCT Solution with ^{64}Cu & ^{67}Cu



MANUFACTURING

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

By Angus Liu · May 5, 2022 12:44pm

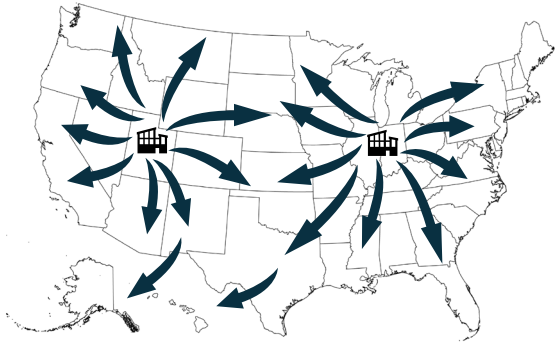
"We have patients on months long waiting lists when this may be all the time they have, and so it's been really disheartening to have to deal with these things"

- 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



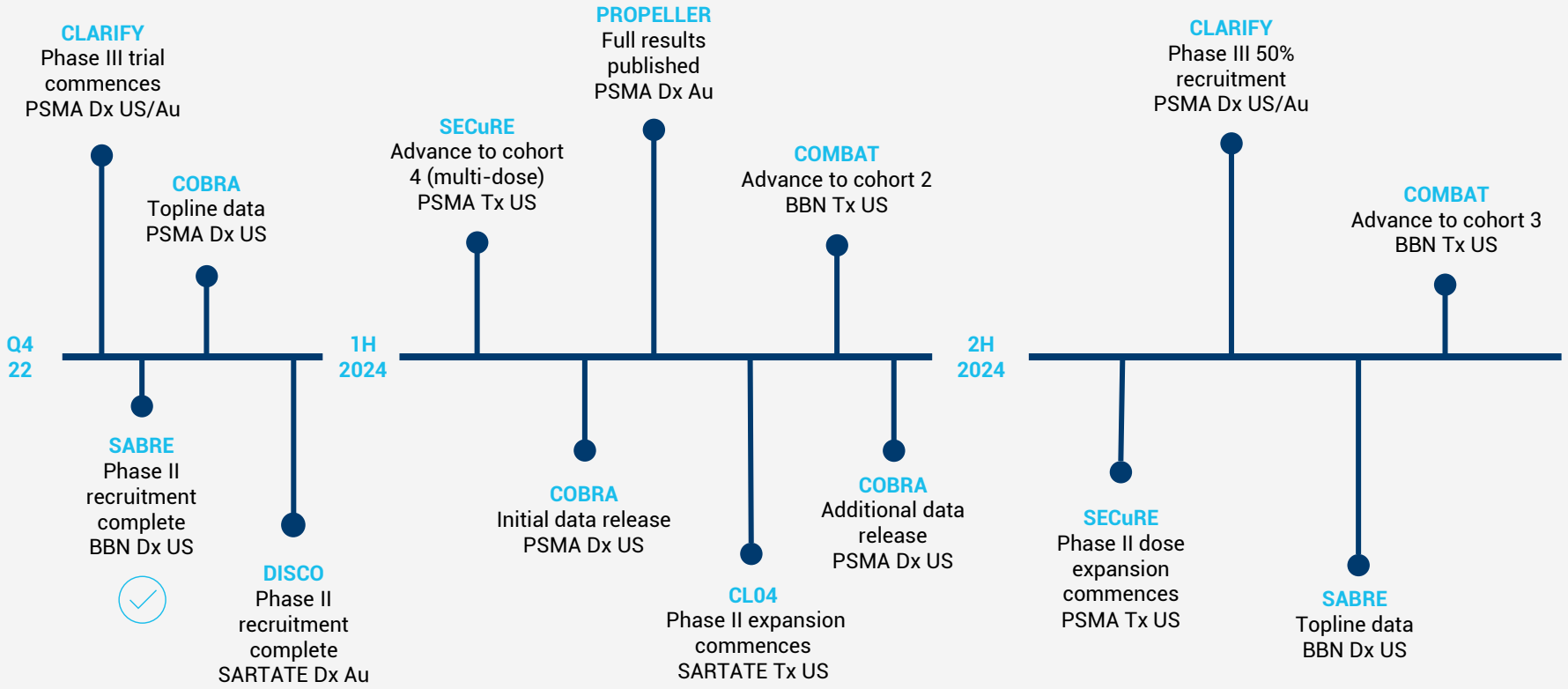
Opportunities with Rhodotron produced ^{67}Cu

- 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

Accelerating clinical progress



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 **~$53.6 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
- **Highly active M&A sector** with numerous recent acquisitions

Thank you

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