**MEDIA RELEASE**

13 June 2023

# Jefferies Healthcare Conference

**Clarity Pharmaceuticals** (ASX: CU6) ("Clarity", "the Company"), a clinical stage radiopharmaceutical company with a mission to develop next-generation products that improve treatment outcomes for children and adults with cancer, is pleased to provide the presentation that was delivered by Clarity's Executive Chairperson, Dr Alan Taylor, at the Jefferies Healthcare Conference in New York.

To watch the webcast recording, please click the link below:

https://wsw.com/webcast/jeff281/cu6/1621620

## About Clarity Pharmaceuticals

Clarity is a clinical stage radiopharmaceutical company focused on the treatment of serious disease. The Company is a leader in innovative radiopharmaceuticals, developing targeted copper theranostics based on its SAR Technology Platform for the treatment of cancer in children and adults.

***www.claritypharmaceuticals.com***

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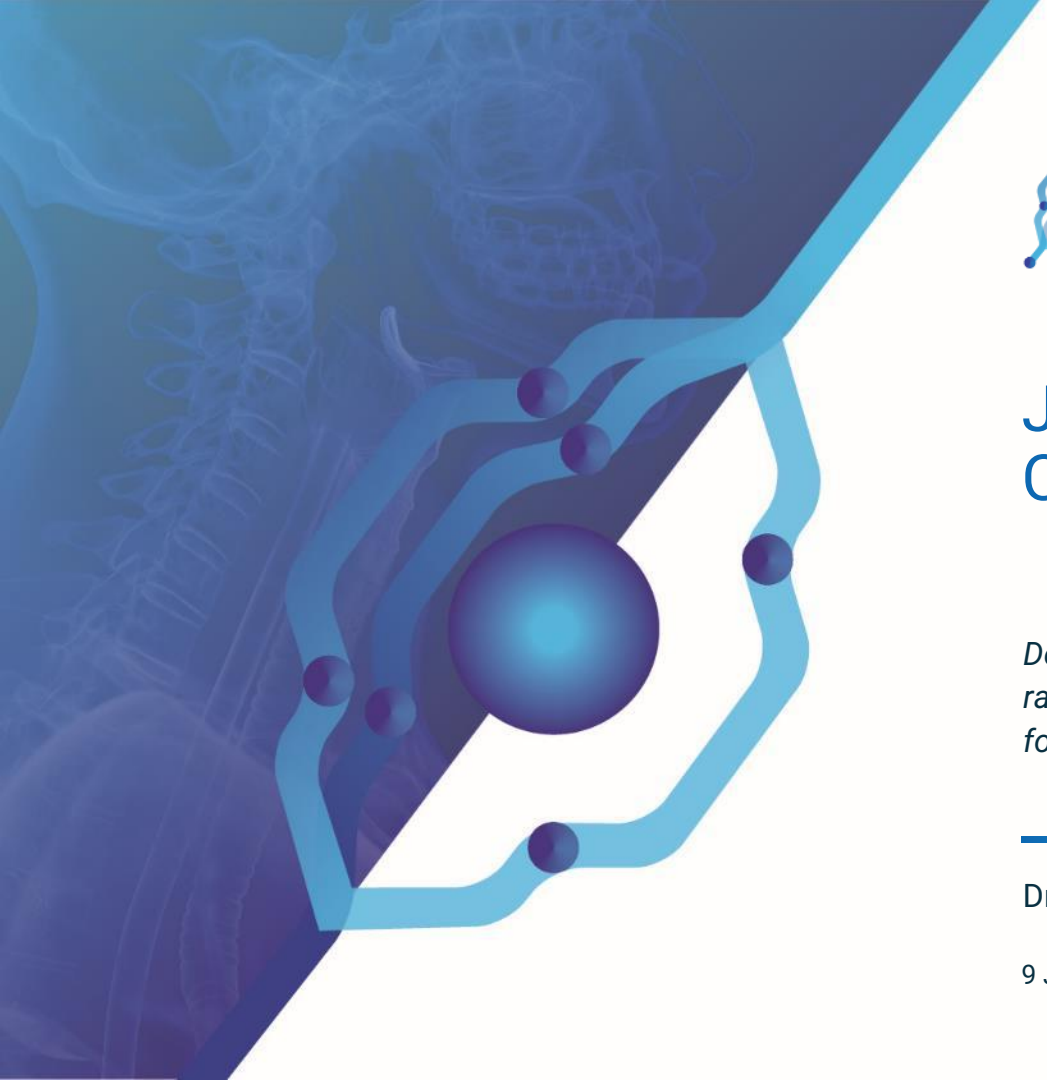
*This announcement has been authorised for release by the Executive Chairman.*



CLARITY PHARMACEUTICALS

# Jefferies Healthcare Conference

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

Dr Alan Taylor, Executive Chairperson

9 June 2023

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# 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**

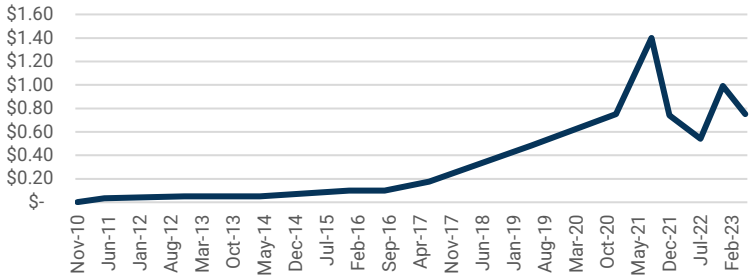
Diverse and in-depth expertise spanning corporate finance, operations, commercialisation & industry

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$0.77** |
| Cash at bank[1] | **A$73M** |
| Shares on issue | **260.4M** |
| Options on issue | **25.5M** |
| Market cap (undiluted)[2] | **A$200.5M** |

1. As at 31 March 2023
2. As at 7 June 2023

## Share price



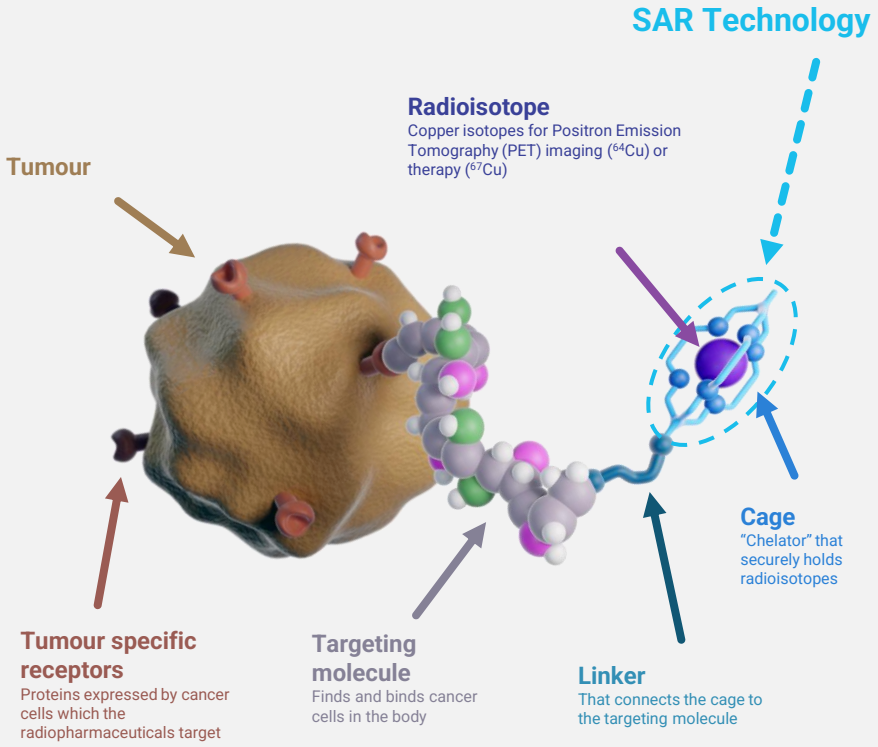

CLARITY PHARMACEUTICALS

# 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 |

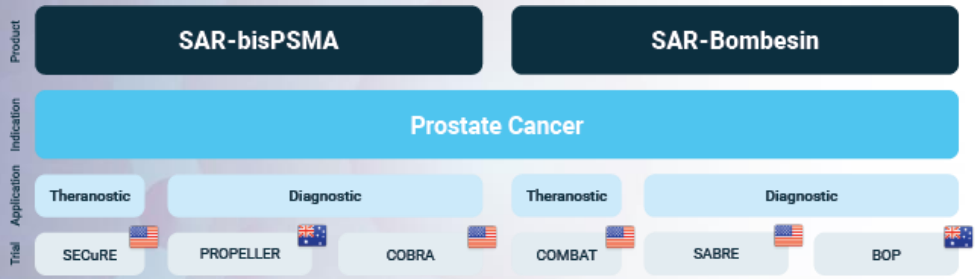
## Therapeutic radionuclides

| | 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) |

# Prostate cancer

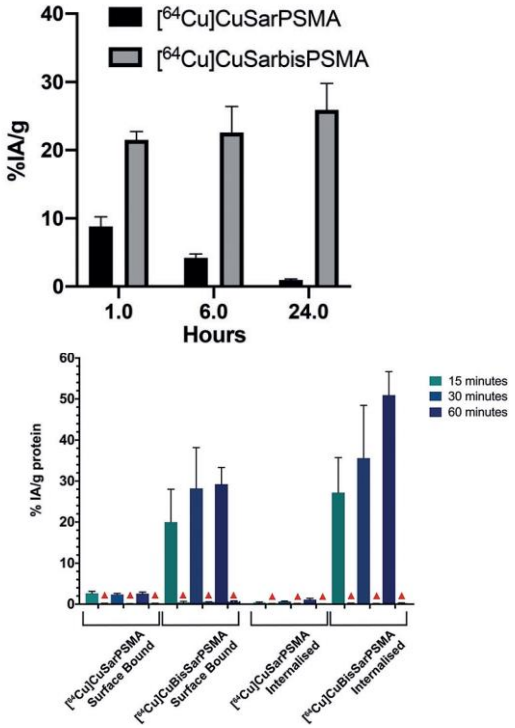
Two product areas: bisPSMA & Bombesin

Four products for diagnosis and therapy

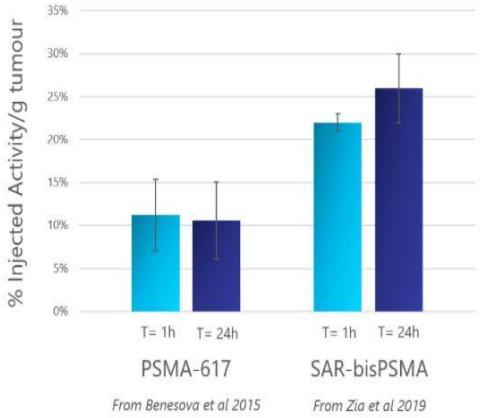


# SAR-bisPSMA

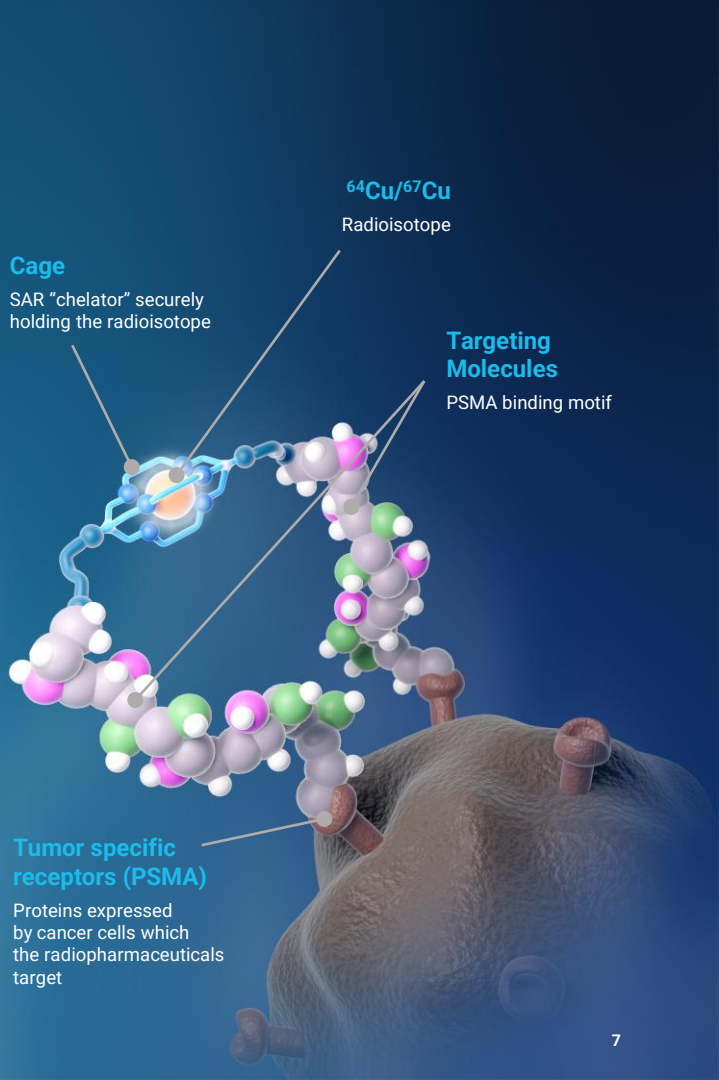
## Superior performance of bisPSMA compared to monomer PSMA




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




Zia et al., 2019. Ang.Chem



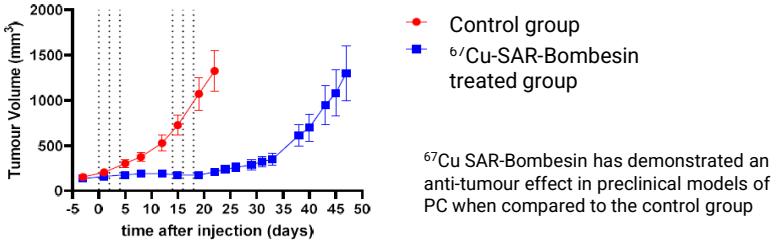
# SAR-Bombesin

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)

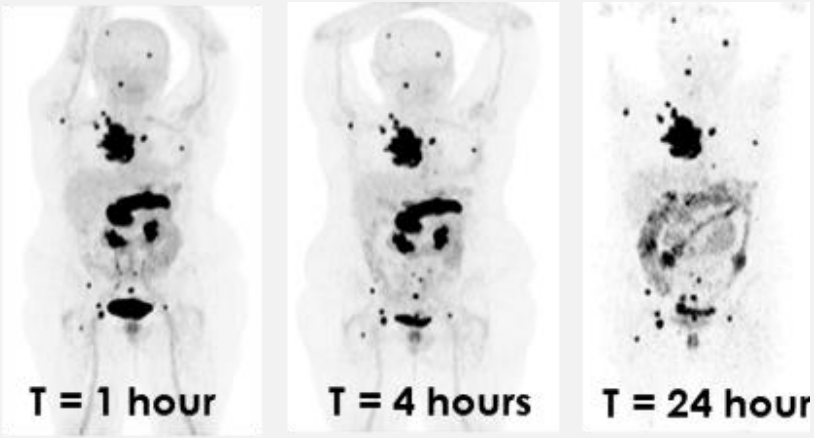
- 75%-100% of PCs express GRPr
- ~20% of PC patients do not express PSMA
- PSMA-negative PC patients will not respond to PSMA imaging or therapy
- SAR-Bombesin is now under investigation as a theranostic as well as a stand-alone diagnostic imaging agent for PC that is PSMA-negative or has a low expression 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

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



# Clarity – Three areas of focus in prostate cancer

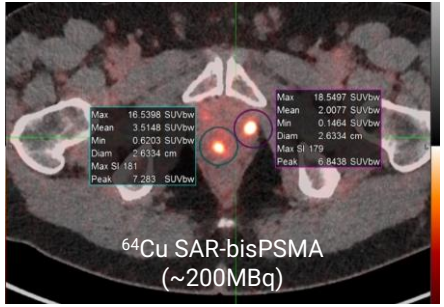
PC is the second largest oncology indication in men with a high unmet need. There are three stages of PC.

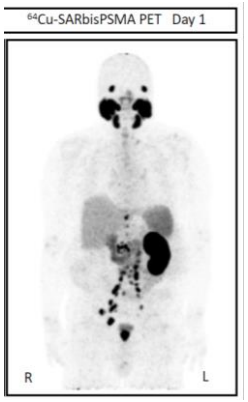
## Primary → Biochemical recurrence (BCR) → Metastatic castration-resistant (mCRPC)

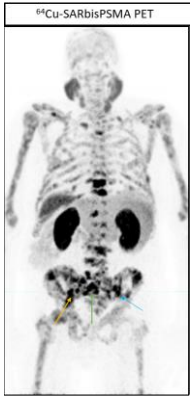
- PC that is localised in the prostate gland with a main (primary) tumour
- Unless disease has spread, most common treatment is surgery called prostatectomy (removal of the prostate) or radiation therapy

- 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




Diagnostics with Cu-64 SAR bis-PSMA

Therapy with Cu-67 SAR bis-PSMA

# Next-generation 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 Q1 23: ~US$195M

Telix: Illuccix® (generic PSMA-11 kit) sales Q1 23: ~ US$66M

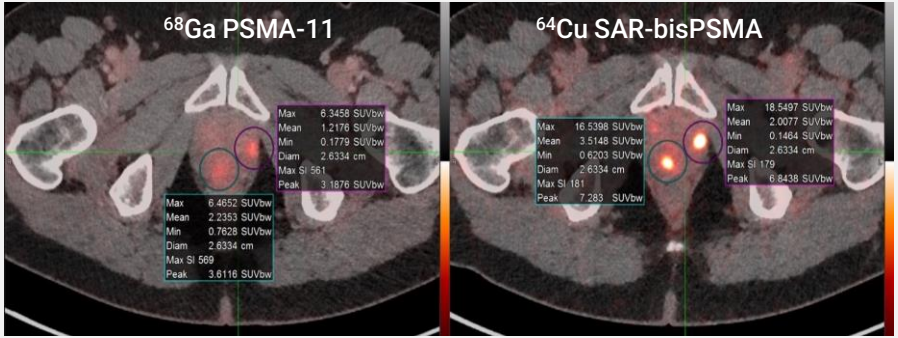
→

Specificity ~ 96% ✓

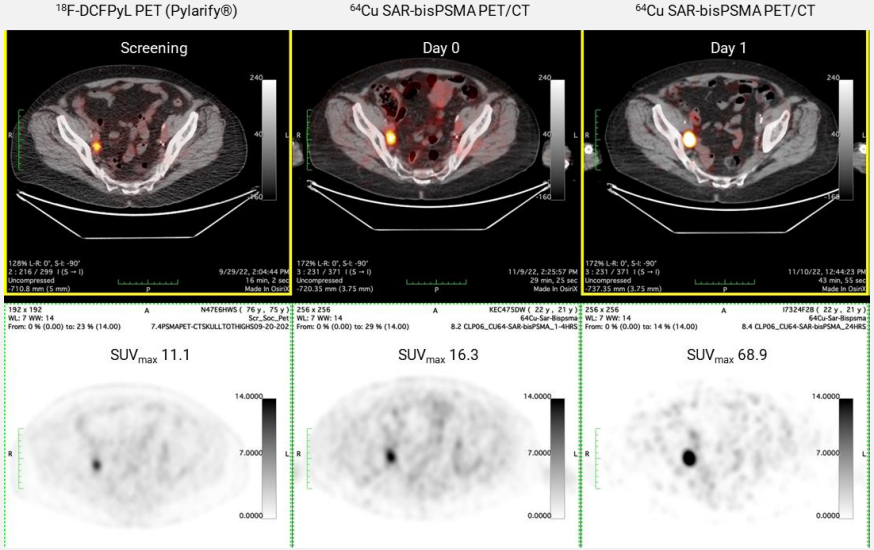
Sensitivity ~ 35% ✗

## 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

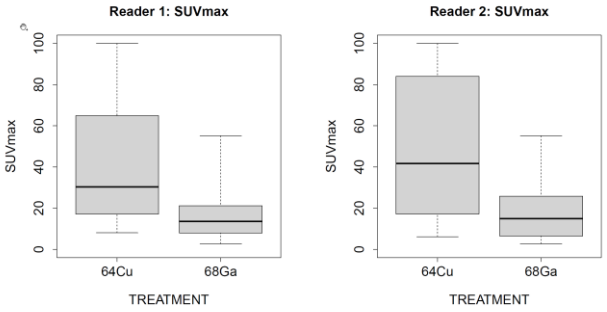


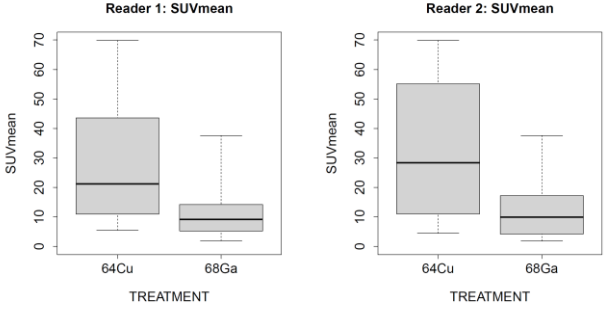

CLARITY PHARMACEUTICALS

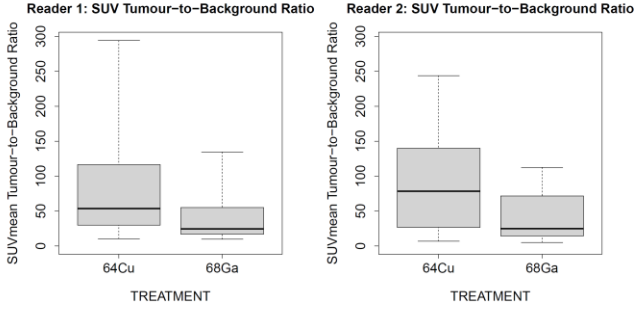
# SAR-bisPSMA diagnostic in untreated, confirmed prostate cancer

PROPELLER

## Comparison of $^{64}$Cu-SAR-bisPSMA PET/CT and $^{68}$Ga-PSMA-11 PET/CT by Reader in all cohorts




## Uptake of $^{64}$Cu-SAR-bisPSMA and $^{68}$Ga-PSMA-11 in concordant lesions

| All Cohorts | Parameter | Imaging | N | Median | IQR | Min | Max | Median Difference | p-value* |
|---|---|---|---|---|---|---|---|---|---|
| Reader 1 | SUVmax | $^{64}$Cu | 28 | 30.26 | 46.9 | 8 | 100 | 14.23 | p < 0.001 |
| | | $^{68}$Ga | 28 | 13.53 | 12.79 | 2.7 | 55.1 | | |
| | SUVmean | $^{64}$Cu | 28 | 21.2 | 32.23 | 5.4 | 69.9 | 9.26 | p < 0.001 |
| | | $^{68}$Ga | 28 | 9.12 | 8.71 | 1.8 | 37.6 | | |
| | TBR | $^{64}$Cu | 28 | 53.55 | 84.45 | 10.3 | 294.1 | 27.94 | p < 0.001 |
| | | $^{68}$Ga | 28 | 24.29 | 36 | 9.6 | 134.4 | | |
| Reader 2 | SUVmax | $^{64}$Cu | 16 | 41.66 | 58.77 | 6.1 | 100 | 27.99 | p < 0.001 |
| | | $^{68}$Ga | 16 | 14.93 | 17.16 | 2.7 | 55.1 | | |
| | SUVmean | $^{64}$Cu | 16 | 28.4 | 37.92 | 4.4 | 69.9 | 18.78 | p < 0.001 |
| | | $^{68}$Ga | 16 | 9.94 | 11.56 | 1.8 | 37.6 | | |
| | TBR | $^{64}$Cu | 16 | 78.37 | 98.97 | 6.7 | 243.9 | 46.93 | p < 0.001 |
| | | $^{68}$Ga | 16 | 24.69 | 52.14 | 5 | 112.4 | | |

*Comparison of imaging methods undertaken with two-sided Wilcoxon signed-rank test.
Note: The lesions were averaged for each patient so that each patient contributes once to the summary statistics.

Concordant lesions on $^{64}$Cu-SAR-bisPSMA and $^{68}$Ga-PSMA-11 PET/CT consistently showed higher SUVmax and SUVmean and tumour-to-background ratios with $^{64}$Cu-SAR-bisPSMA compared to $^{68}$Ga-PSMA-11 in all cohorts of the PROPELLER trial

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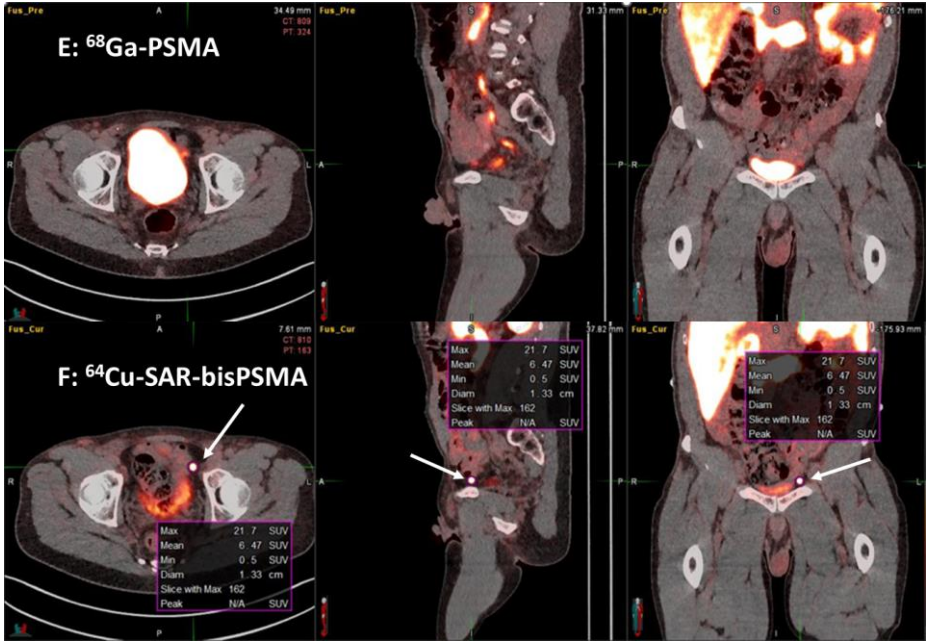
# SAR-bisPSMA diagnostic in untreated, confirmed prostate cancer

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.




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

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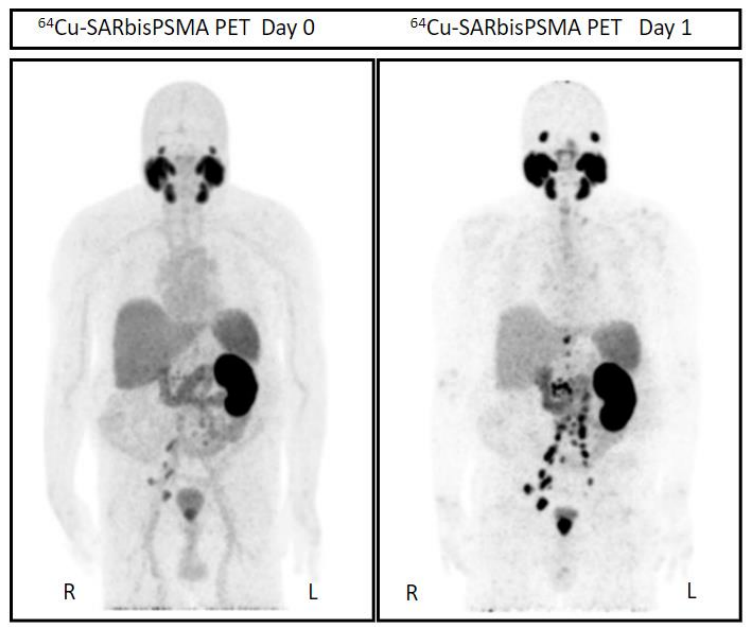
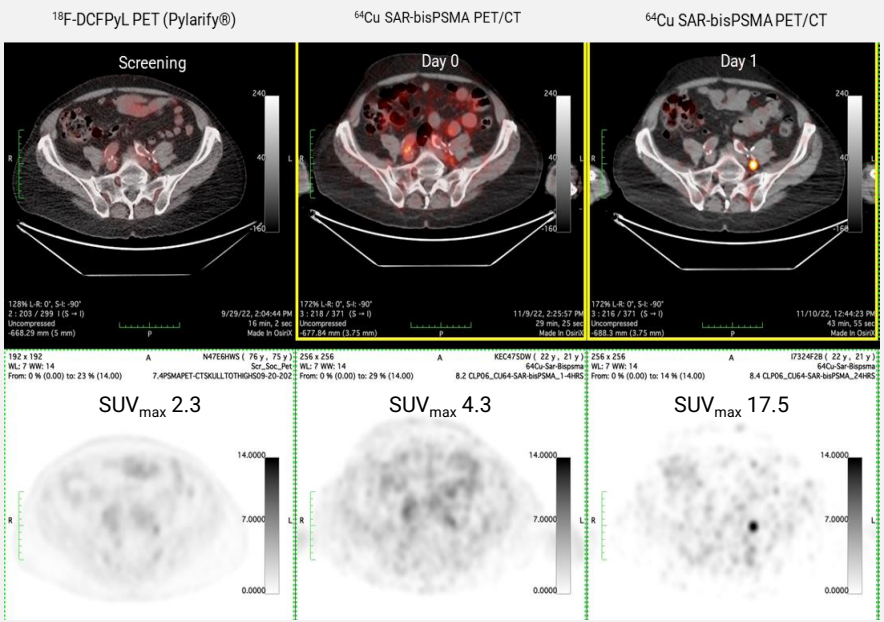
# Copper brings significant additional advantages

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**

**Images from Clarity's COBRA study**



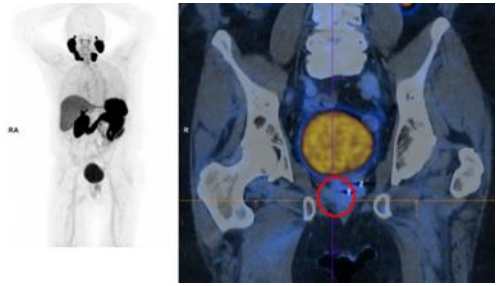
# SAR-Bombesin in BCR PC

## Benefits

- A number of PC lesions do not express PSMA or have low expression of the receptor
- In patients with BCR PC, their PSA levels kept rising following curative treatment, indicating the cancer returned, however, 1st generation PSMA scans were unable to visualise the cancer
- SAR-Bombesin targets GRPr, which has the potential to detect PSMA-negative lesions
- SAR-Bombesin could be used in combination with diagnostic PSMA agents to ensure both PSMA- and GRPr-positive tumours are detected, or as a stand-alone radio-diagnostic in PSMA-negative PC

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

$^{68}$Ga PSMA-11



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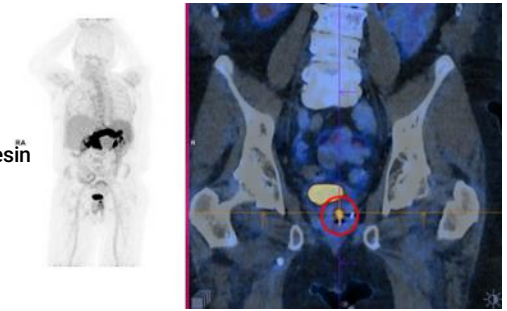
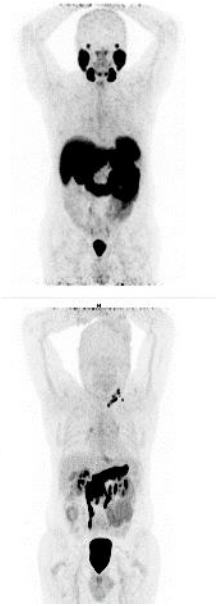
$^{64}$Cu SAR-Bombesin



$^{68}$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



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$^{64}$Cu SAR-Bombesin

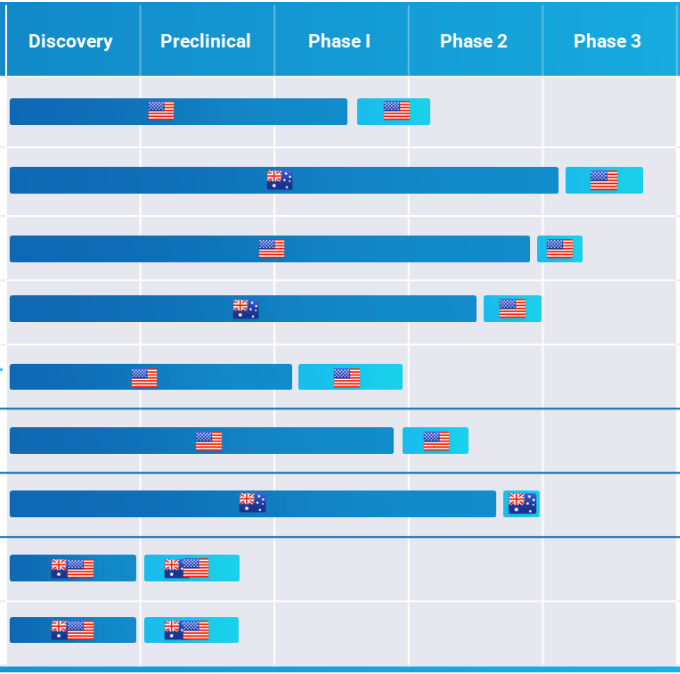
$^{68}$Ga PSMA-11 (top) image of a PSMA-negative patient with history of prostate cancer (a rising PSA score of 25 ng/mL) and $^{64}$Cu SAR-Bombesin PET/CT image of the same patient (bottom)

# Clinical development in multiple cancers

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

## Clinical development pipeline as of 7 June 2023

| Indication | Product | Application | Current Trial | Next Milestone |
|---|---|---|---|---|
| Prostate Cancer | SAR-bisPSMA | Theranostic mCRPC | SECURE | Advance to cohort 3 |
| | SAR-bisPSMA | Diagnostic in pre-radical prostatectomy | PROPELLER | Phase III opens for recruitment |
| | SAR-bisPSMA | Diagnostic in BCR PCa | COBRA | COBRA top line data |
| | SAR-BBN | Diagnostic in BCR PCa | SABRE | SABRE 50% recruitment |
| | SAR-BBN | Theranostic mCRPC | COMBAT | Recruitment commences |
| Neuroblastoma | SARTATE™ | Theranostic | CL04 | Advance to cohort 4 |
| NETs | SARTATE™ | Diagnostic | DISCO | DISCO recruitment complete |
| SAR Discovery Platform | Undisclosed | Undisclosed | | |
| | Undisclosed | Undisclosed | | |

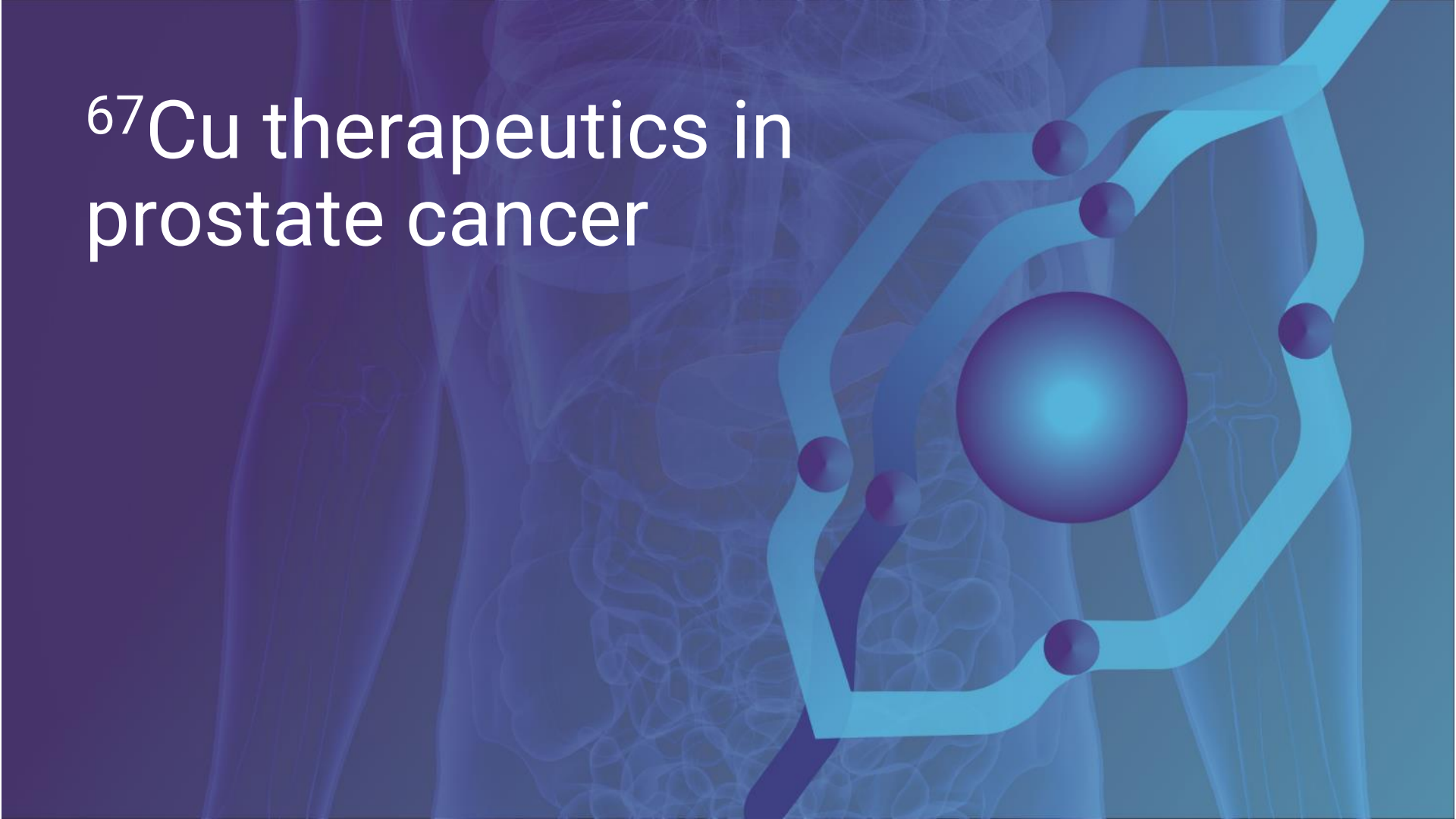



Current progress | 12 month progress

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

All US studies are conducted under IND

# $^{67}$Cu therapeutics in prostate cancer



# 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 recruitment now closed (8GBq dose level)

### Next milestone

- Cohort 3 open for recruitment Q3 23

## 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

- Opening for recruitment June 23
- Cohort 1 will dose at 6GBq $^{67}$Cu SAR-Bombesin

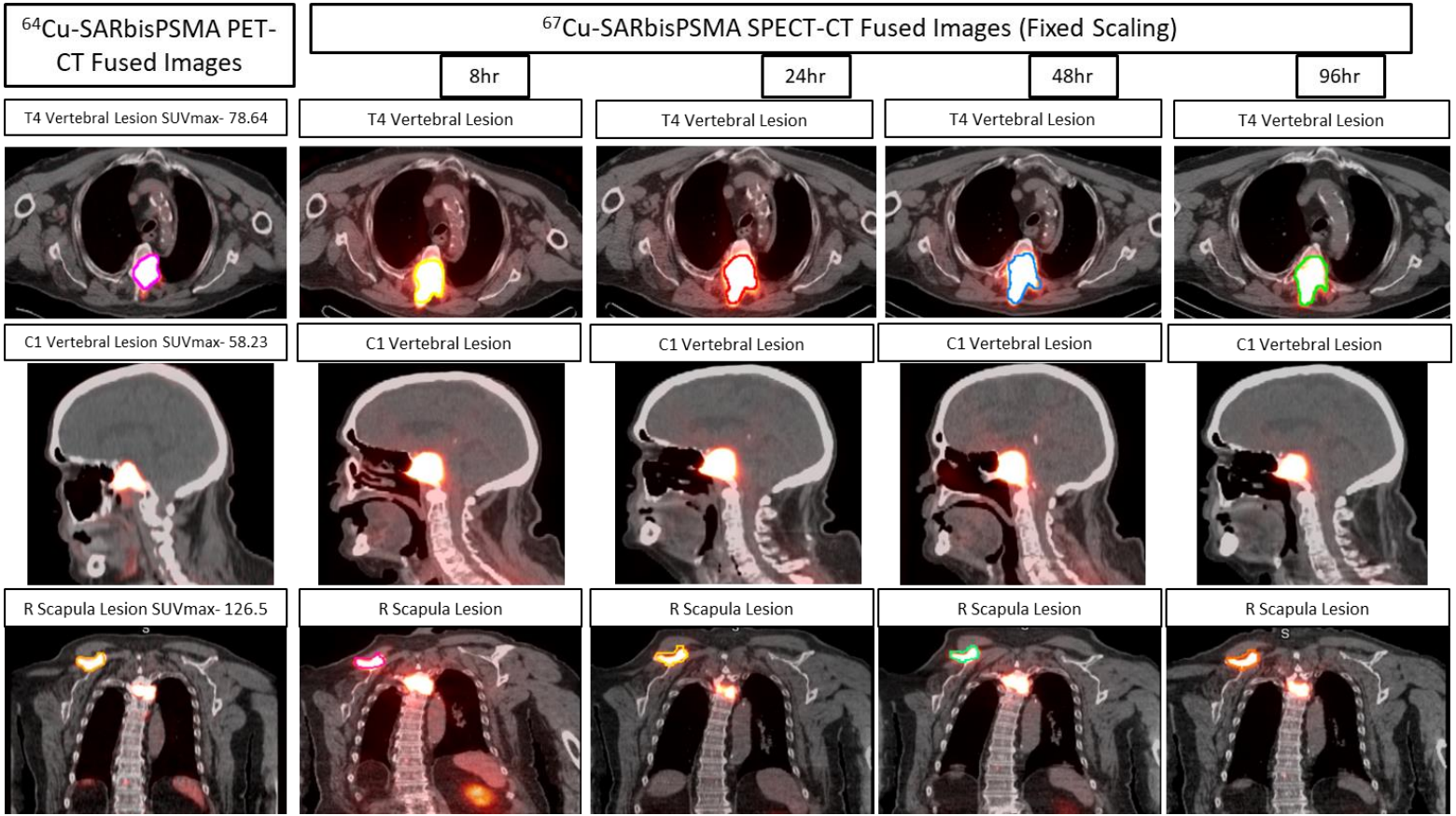
### Next milestone

- Cohort 2 open for recruitment

*SECuRE clinicaltrials.gov identifier: NCT04868604*

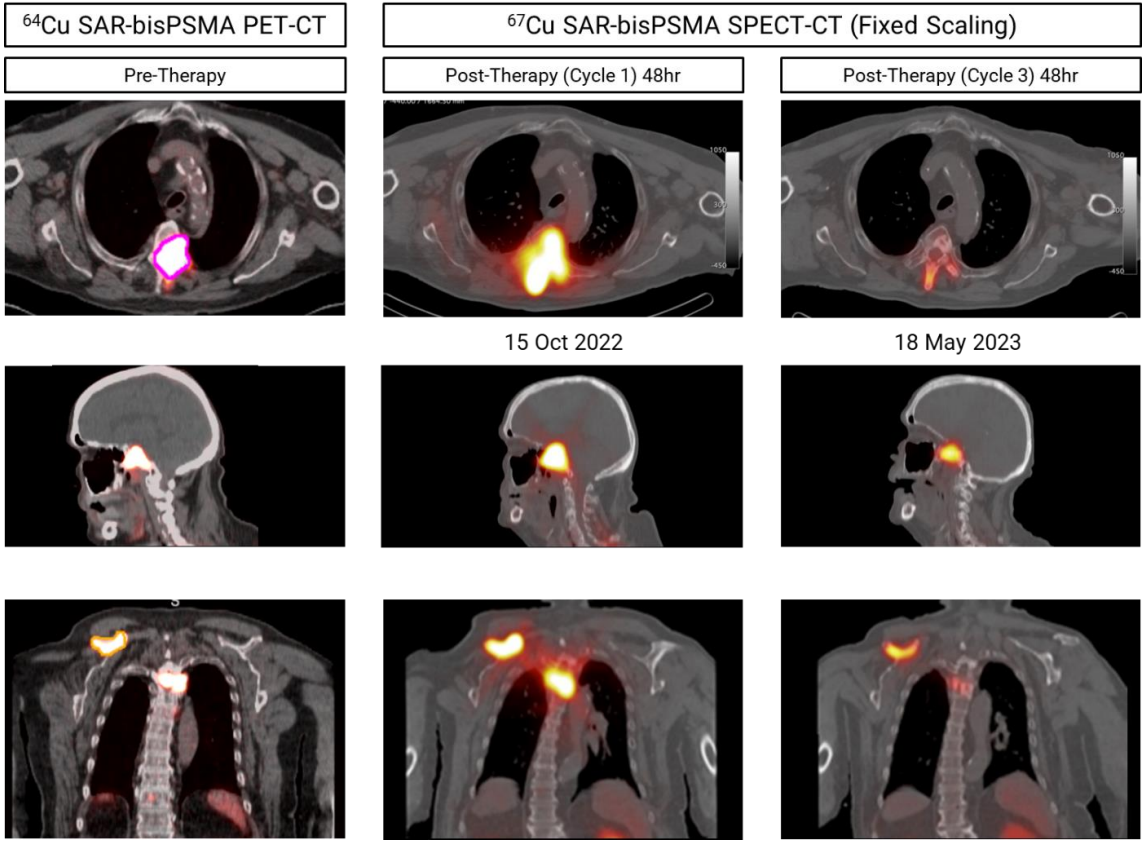
*COMBAT ClinicalTrials.gov identifier: NCT05633160*

# Cohort 1 (4GBq dose level)



# US FDA Expanded Access Program

- Additional therapy cycles of $^{67}$Cu SAR-bisPSMA 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 three doses, signaling tumour shrinkage
- Same patient experienced a reduction in PSA levels >50% following the first dose

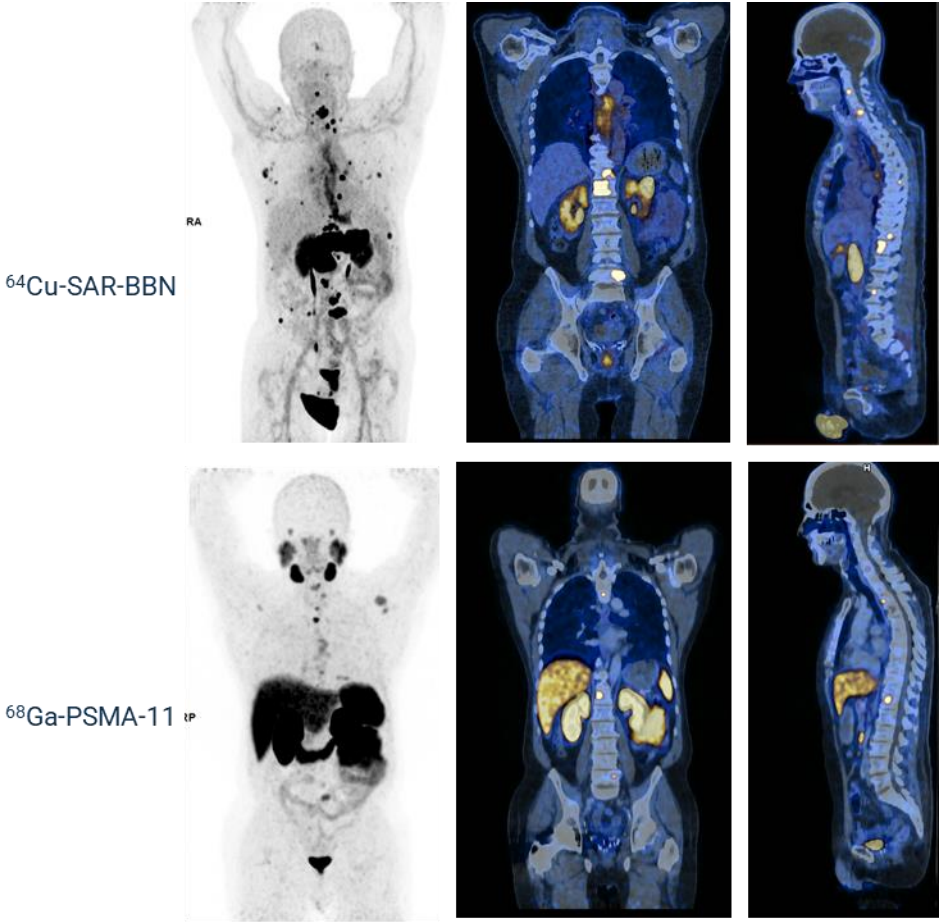


# $^{67}$Cu SAR-Bombesin in mCRPC

## 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.

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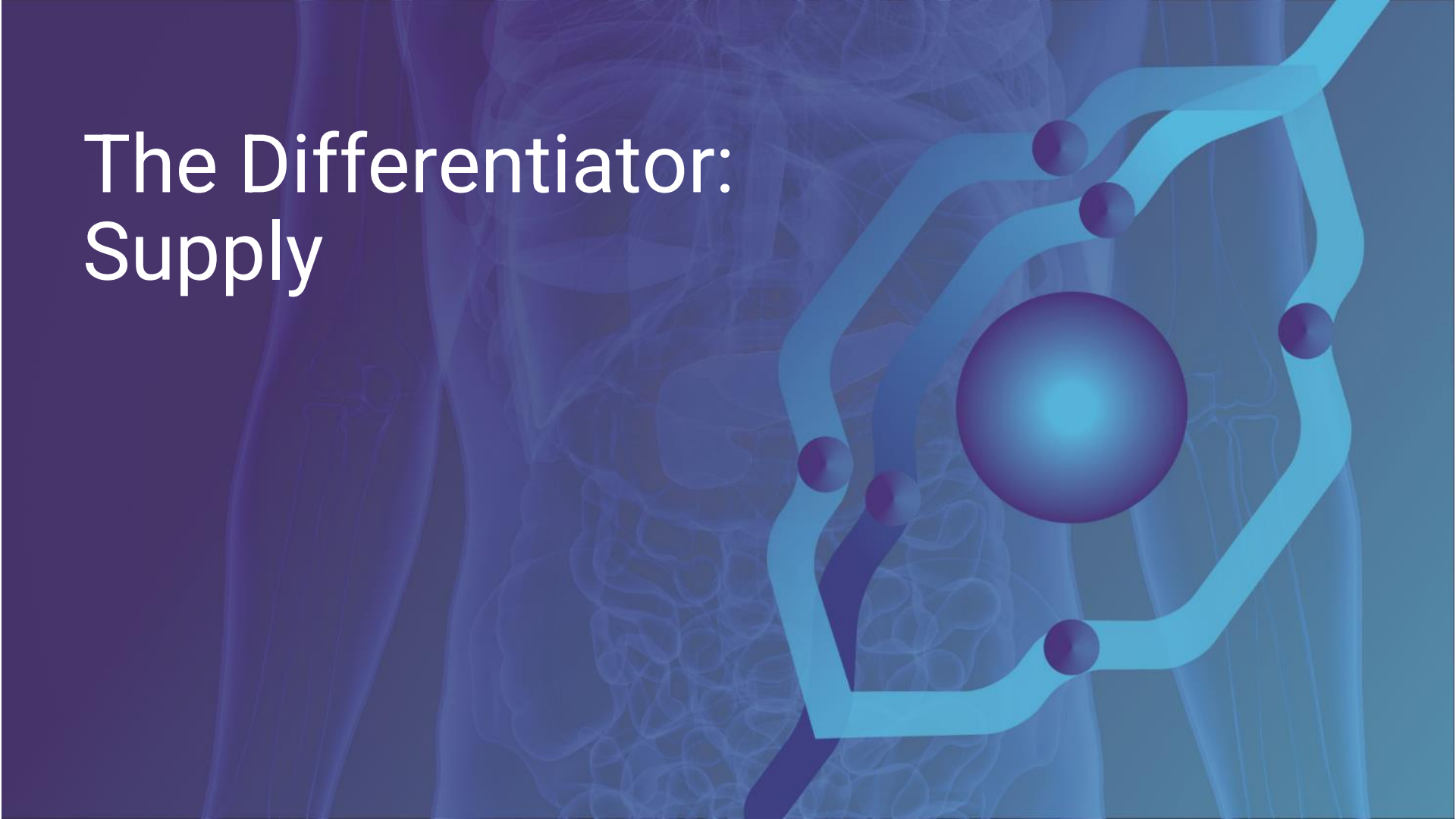
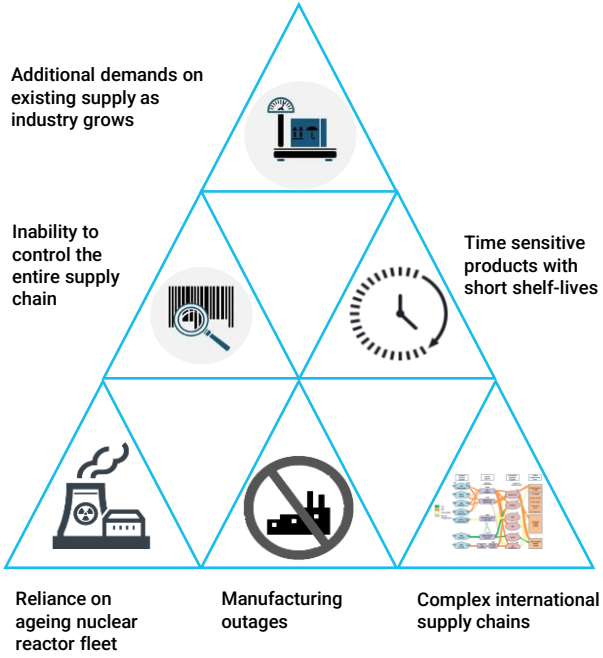
# The Differentiator: Supply



# Current industry challenges




# Combined with a history of supply issues

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

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

Dear Dr. Marzella and Dr. Zadecky,

MANUFACTURING

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

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

nature › news › article

Published: 12 September 2016

**Reactor shutdown threatens world's medical-isotope supply**

NewScientist

SUBSCRIBE AND SAVE 60%

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

Bayer Suspends Production of Radium-223 Due to Manufacturing Problem

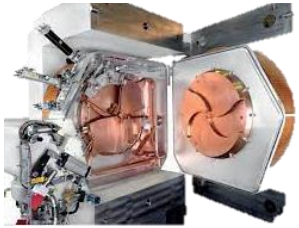
October 17, 2014
Beth Fand Incollingo

# Creates challenges for prescribers

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

# TCTs: Universal access to diagnostics and therapy

Solving the challenges of current generation diagnostic radiopharmaceuticals



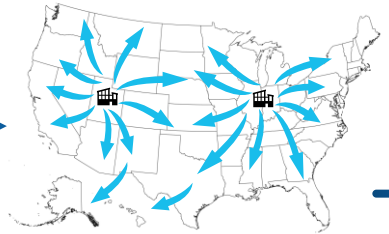
**Cu-64 produced daily on 2 cyclotrons**

- >100Ci/day possible
- >3500 patients doses/day
- >900,000 patient doses a year

**Cu-67 produced daily on Rhodotrons**

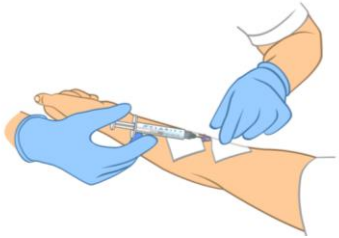
- Domestic US production
- Easily scalable at low cost
- No reliance on nuclear reactors or the uranium fuel cycle
- A single Rhodotron can provide enough Cu-67 to support a commercial product

**Manufactured in less than 25 minutes** through an automated and rapid room temperature process



**Shipped as patient-ready doses**

- ~48 hour product shelf-life
- Delivery on demand across the USA
- 5 days a week availability



**Patient injected and scanned**

- Convenient and flexible scheduling
- Option to re-image at later time point
- No waiting time for product
- >1M patient doses available / year
- (3500 * 365)

# Enabling universal access to PET imaging with $^{64}$Cu

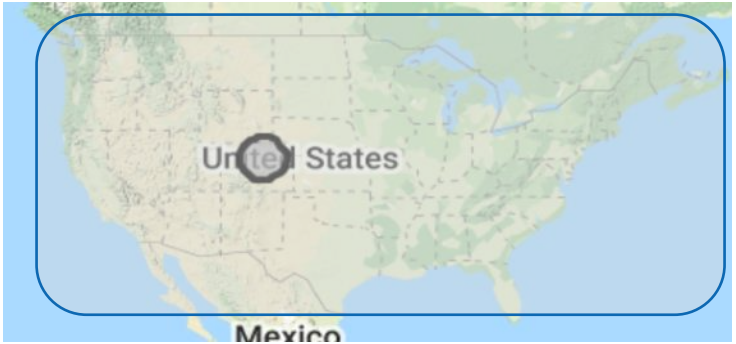
## $^{68}$Ga and $^{18}$F

- Regional availability issues
- Limited scope for future upscaling
- Little patient flexibility with 3-12 hour product shelf life
- No opportunity for delayed imaging timepoints
- Complicated and resource intensive local production requirements
- Relatively high external radiation exposure
- OPEX and CAPEX needed in every market

"An F-18 PET center can provide doses for up to ten medical centers or PET cameras running patients in parallel"[1]

"Each (Ga-68) generator can only produce a sufficient amount of Ga-68 each day for a limited number of patients"[2]

The future of PET radioisotope supply is dependable, scalable and customer focused




## $^{64}$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
- Delivered as a ready-to-use cGMP product
- 9-22 times lower exposure than commonly used $^{18}$F products
- The ability to centralise investments and supply the country

*1. MEDray intel, Nuclear Medicine Report and Directory Part 1, Volume 8, 2021 Page 163*
*2. Krishan Kumar.Cancer Biotherapy and Radiopharmaceuticals.Apr 2020.163-166*

CLARITY PHARMACEUTICALS

# Next generation of therapeutics with $^{67}$Cu

## $^{177}$Lu

- Relies on antiquated, unreliable and government subsidised nuclear reactor infrastructure
- Not easily scalable due to investment requirements for new nuclear reactor construction
- Existing supply chain already strained, with demand soon outstripping supply
- Supply chain dependence on international shipments
- Expensive and environmentally unfriendly inputs for production ($^{235}$U, $^{176}$Yb)
- Long lived $^{177m}$Lu impurity from c.a. production can create radioactive waste handling issues at sites

**Eliminating dependency on the limited number of aging nuclear reactors for therapeutic radioisotope supply**

## $^{67}$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

# Targeted Copper Theranostics

## Clarity's solution to theranostic isotope supply threats

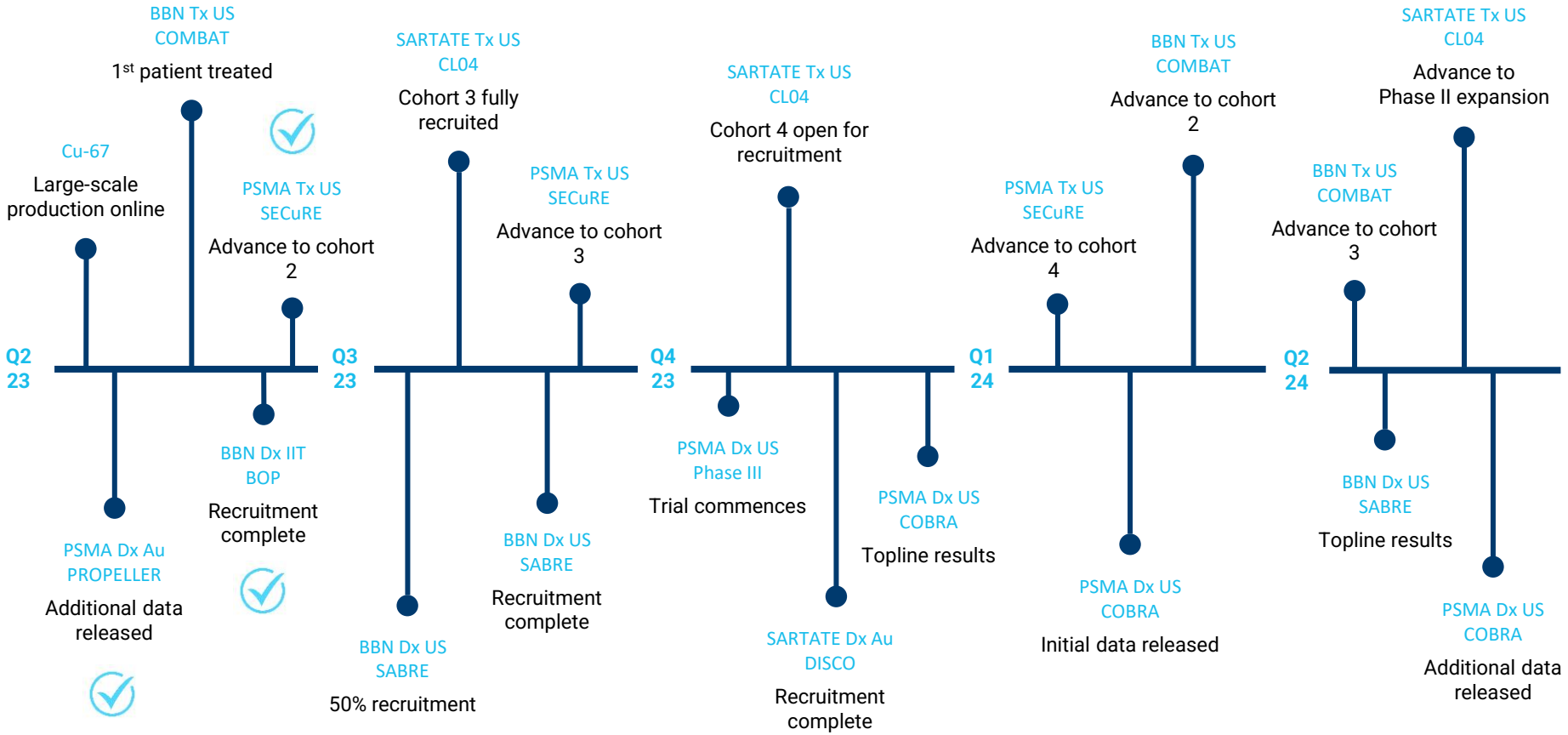
- No reactors
- No time sensitive international supply chains
- No local production requirements
  - Reduce costs
  - Reduced patient safety risk
  - Universal availability
- Economies of scale from the same manufacturing process
- Ability to quickly integrate new products
- Centerpiece for a customer facing marketing strategy

## The environmental considerations of TCT

- As the number of patient treatments increases, environmental factors will impact the selection of theranostic radiopharmaceuticals
- Production of $^{64}Cu$ and $^{67}Cu$ have:
  1. favorable environmental characteristics;
  2. a relatively small infrastructure footprint;
  3. do not use nuclear reactors and enriched uranium;
  4. avoid the creation of long-lived radioactive impurities;
  5. lack significant radioactive waste disposal issues; and
  6. use more readily available target materials which do not employ rare earth elements.
- These factors will significantly reduce the environmental impact compared to current generation of theranostics based on $^{68}Ga$ or $^{177}Lu$
- This is highly relevant considering the forecasted growth of theranostics over the next decade

# Inflection points in the next 12 months

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
- 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 **~$73 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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