



Wilson's Drug and Device Conference

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

27 October 2023

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Clarity in a nutshell (ASX:CU6)

Proprietary SAR Technology: a true platform technology

Platform of best-in-class products in clinical development protected by 24 patent families, offering high accuracy and precision for both diagnosing and treating disease

Environmental advantages over current isotopes

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

Global leader in Targeted Copper Theranostics (TCTs)

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

Targeted clinical development strategy

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

Significant supply, logistical, dependability and scalability benefits

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

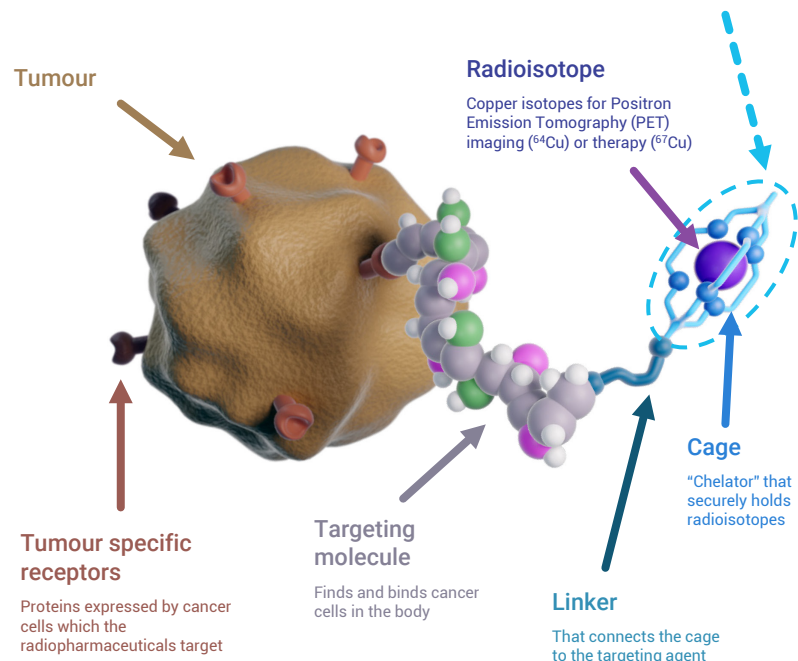
Highly experienced leadership team

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

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

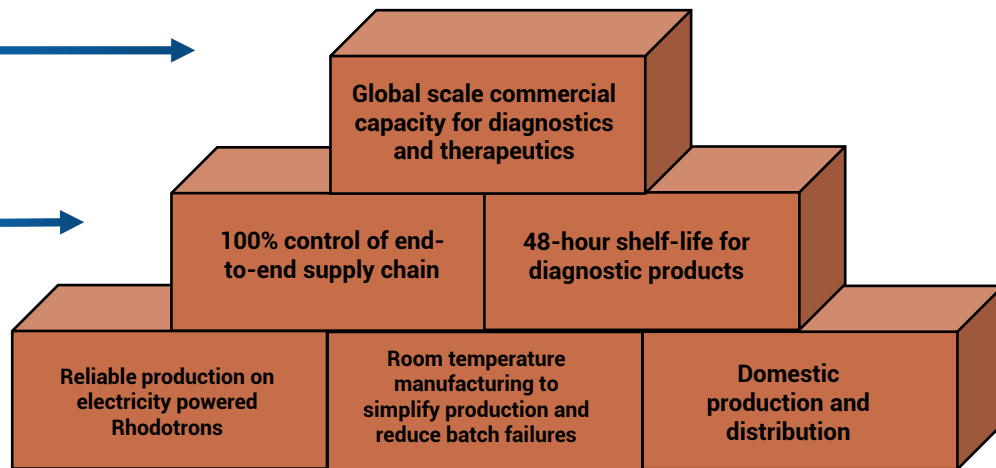


A proprietary, highly specific and highly stable bifunctional cage (chelator) with a superior ability to retain copper isotopes within it and prevent their leakage into the body



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

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

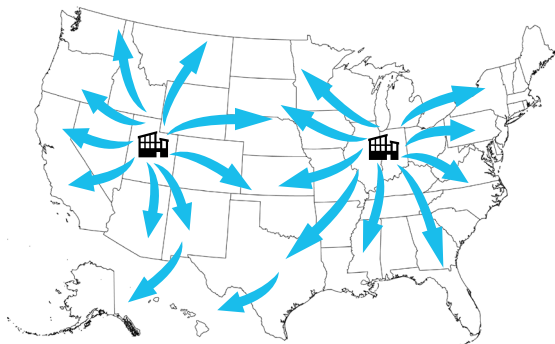
"We have patients on months long waiting lists when this may be all the time they have, and so it's been really disheartening to have to deal with these things"

- 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

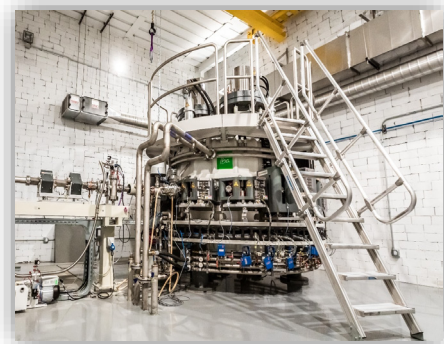
Opportunities with ^{64}Cu (half-life = 12.7h)

- 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

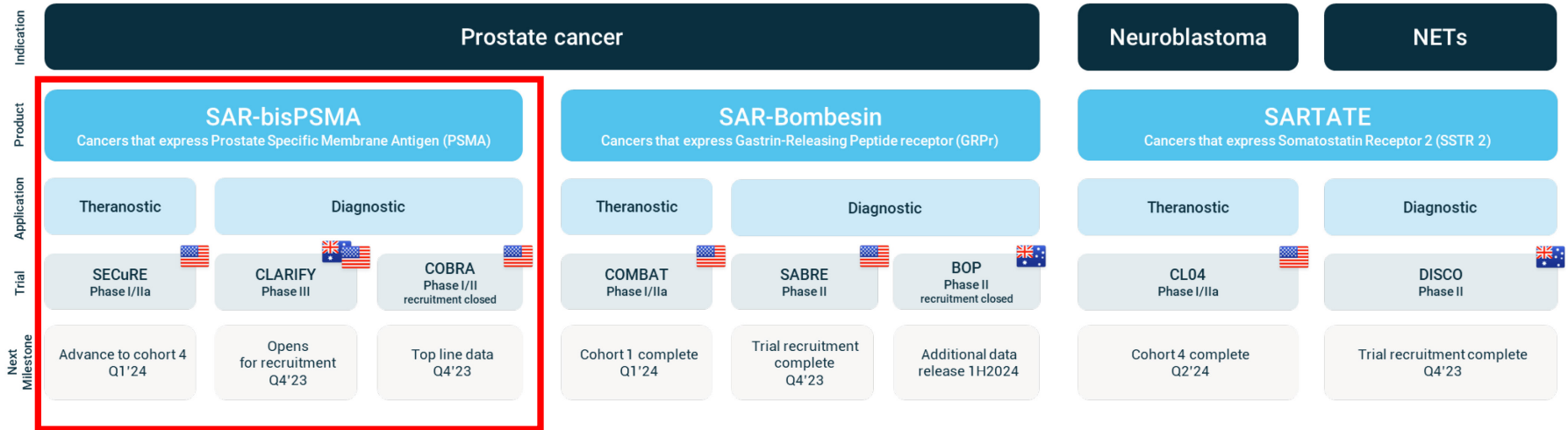


“Access to reactors will soon become the bottleneck for ^{177}Lu ”¹

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

Three core product areas in US clinical trials

Clarity has potential to address multiple oncology indications with unmet needs through a range of products and their applications. These include large indications, such as prostate and breast cancers, as well as small and orphan indications, such as neuroendocrine tumours (NETs) and neuroblastoma, an aggressive childhood cancer.



Each product targets a distinct receptor present on the surface of cells of a range of cancers (i.e. PSMA, GRPr or SSTR2)

Each product class can be used as:

- A stand-alone ⁶⁴Cu-based diagnostic
- Combined as a theranostic using ⁶⁴Cu-labelled products to select patients for therapy with ⁶⁷Cu-labelled products

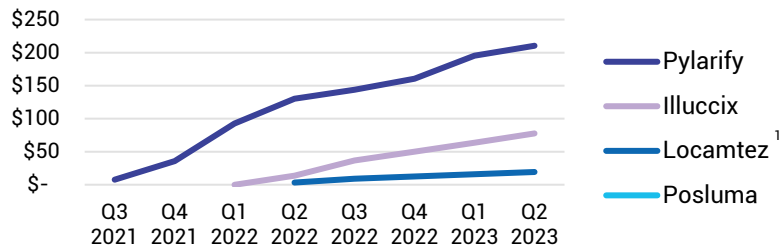
SAR-bisPSMA market opportunity

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

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**

Quarterly US Sales (\$M USD) - PSMA PET Diagnostics



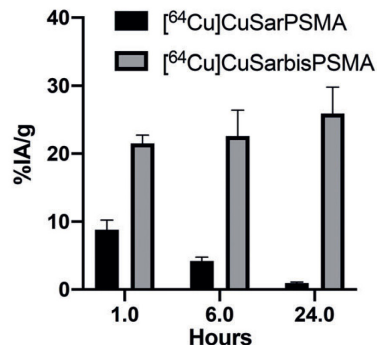
PSMA based therapy (mCRPC)

- Current US patient pool for Pluvicto (post-chemo mCRPC): ~25,000 patients
- Future US patient pool for Pluvicto (pre-chemo mCRPC): ~44,000 patients
- Pluvicto (¹⁷⁷Lu PSMA-617) pricing: US\$255,000 for 6 therapy cycles
- Current US market opportunity (post chemo): **>US\$5Bn**
- Future US market opportunity (including pre-chemo): **>US\$10Bn**
- Novartis 1H 23 Pluvicto sales were ~US\$450M despite the ongoing supply challenges and are expected to exceed US\$1B in sales by EOY 2023 (post-chemo mCRPC only)

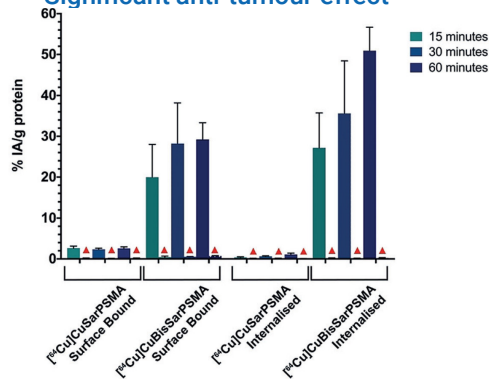
¹Locametz sales estimated at 25% of Illuccix sales

Not all PSMA targeting agents are created equal

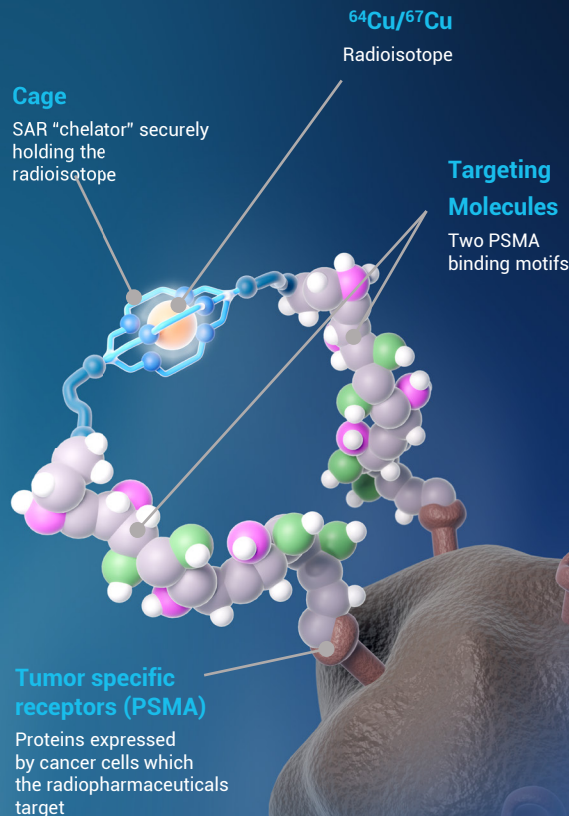
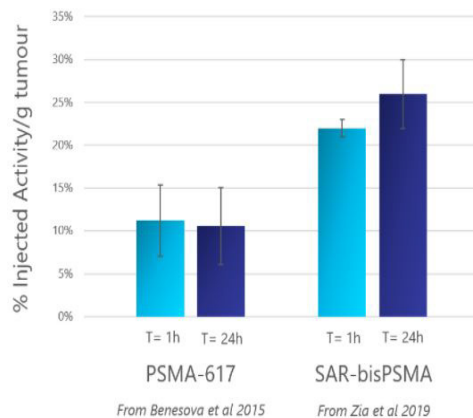
Superior performance of SAR-bisPSMA compared to monomer SAR-PSMA



Significant anti-tumour effect



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

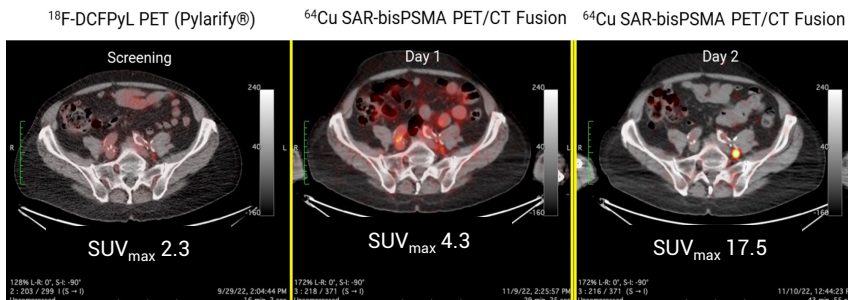
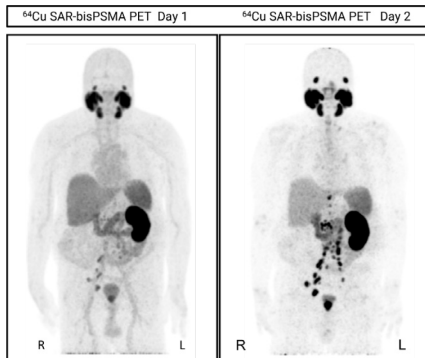


Diagnostic program with ^{64}Cu SAR-bisPSMA

Improved uptake of SAR-bisPSMA may support better diagnosis compared to first-generation PSMA PET agents. Currently approved PSMA agents have high specificity (~96%) but low sensitivity (~35%).

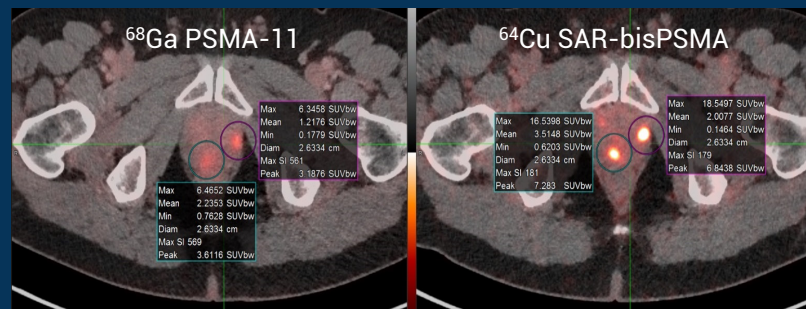
Biochemical Recurrence: Comparison with PYLARIFY® – COBRA study

Phase II study examining the ability to detect recurrence of prostate cancer using same day and next day imaging. Recruitment complete, topline results expected Q4 23



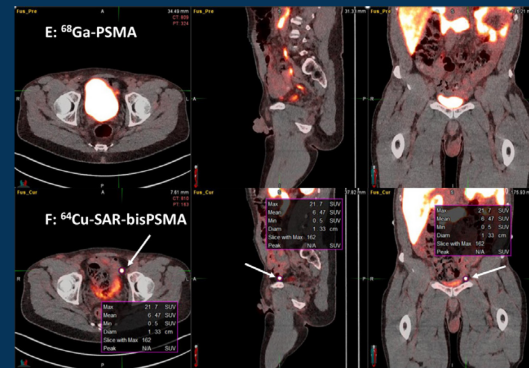
Initial staging – Clarity's PROPELLER study

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



Initial staging – Moving into Phase III with CLARIFY

Registrational study using ^{64}Cu SAR-bisPSMA to detect regional nodal metastasis with both same day and next day imaging in 383 participants. Commencing Q4 23.

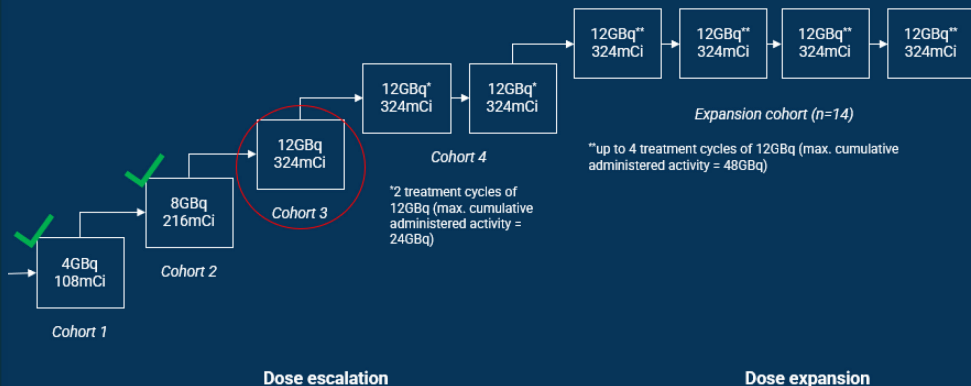


Therapy program with ^{67}Cu SAR-bisPSMA

Currently recruiting into cohort 3 in the US-based study

Trial overview

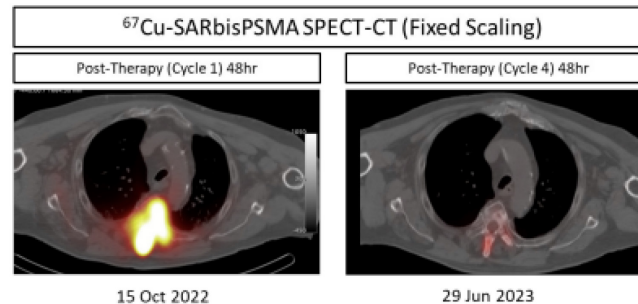
- Phase I/II study in mCRPC
- Participants do not need to have received chemotherapy
- Dose escalation followed by cohort expansion with up to 4 cycles of therapy



Trial highlights to date

- Now recruiting in cohort 3 at 12GBq dosing (Pluvicto dose capped at 7.4GBq)
- 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

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

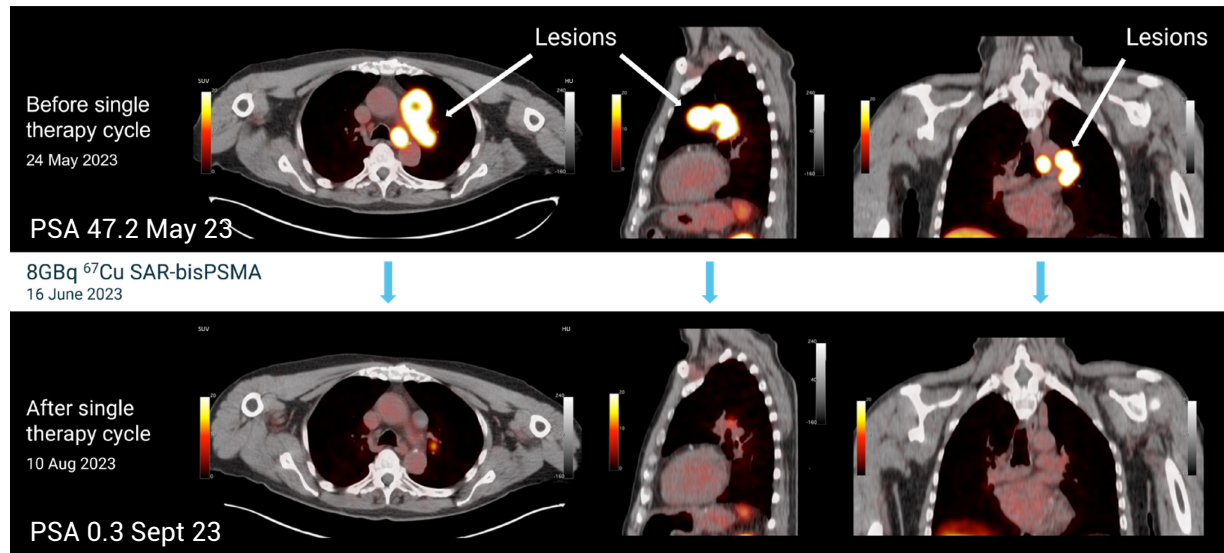


15 Oct 2022

29 Jun 2023

^{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

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 (as of 30 June 23)** 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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