



# Managing Director's presentation

Annual General Meeting  
20 November 2024

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Michelle Parker

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# Key FY24 highlights

## CLINICAL & REGULATORY

- Actively progressing 7 clinical trials + 1 IIT of Clarity's three key product areas
- <sup>64</sup>Cu-SAR-bisPSMA Phase III diagnostic trial ongoing with another Phase III trial commencing shortly
- Fast-Track Designation for <sup>64</sup>Cu-SAR-bisPSMA pre-prostatectomy
- Initial therapy data with <sup>67</sup>Cu-SAR-bisPSMA is very encouraging

## PEOPLE & CULTURE

- Grown the team to 62 employees in the U.S. and Australia
- Approx. 15 promotions in the last year
- Growing senior executive team & aligning roles of existing team members

## OPERATIONS

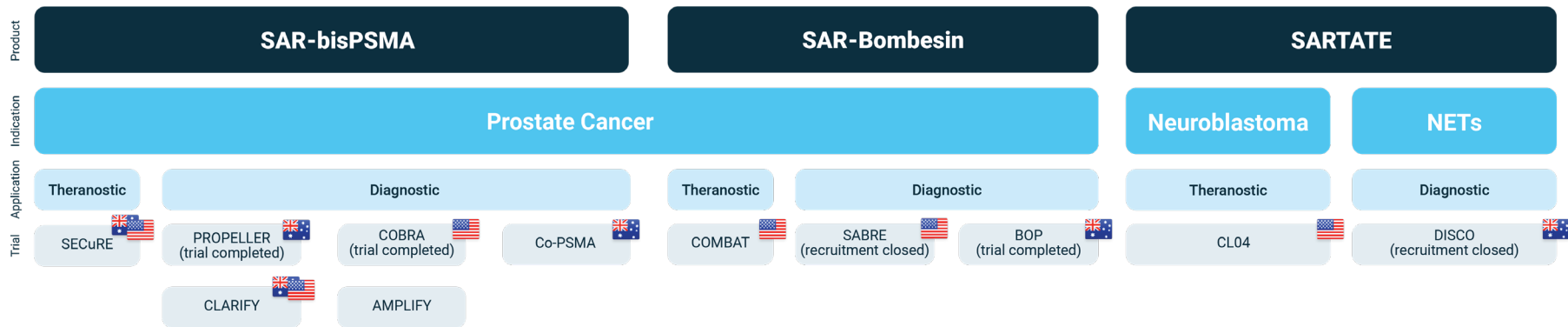
- NorthStar manufacturing commercial scale Cu-67 and <sup>67</sup>Cu-SAR-bisPSMA final drug product under one roof for Phase I/II and Phase III trials
- Nucleus RadioPharma manufacturing <sup>67</sup>Cu-SAR-bisPSMA drug product for Phase I/II and Phase III trials
- SpectronRx manufacturing Cu-64 and <sup>64</sup>Cu-SAR-bisPSMA diagnostic product
- Supply agreement for Ac-225 with TerraPower

## FINANCIAL

- Strong cash balance of \$123.7 million as at 30 September 2024
- Anticipated R&D tax incentive for FY24: ~\$11 million
- Cash runway to fund existing trial pipeline and provide cash runway to 2026
- Continued strong capital markets for radiopharm

# Three core product areas in 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 class can be used as:

- A stand-alone  $^{64}\text{Cu}$ -based diagnostic
- Combined as a theranostic using  $^{64}\text{Cu}$ -labelled products to select patients for therapy with  $^{67}\text{Cu}$ -labelled products

# Clinical stage assets in multiple cancers

Clarity's products are progressing through sponsored clinical trials in the U.S. and Australia

## Clinical development pipeline as of 20 November 2024

Indication	Product	Application	Current Trial	Discovery	Preclinical	Phase I	Phase 2	Phase 3
Prostate Cancer	SAR-bisPSMA	Theranostic mCRPC	SECURE	[Progress bar with US and AU flags]			[Progress bar with US and AU flags]	
	SAR-bisPSMA	Diagnostic in pre-radical prostatectomy	CLARIFY			[Progress bar with AU and US flags]	[Progress bar with AU and US flags]	[Progress bar with AU and US flags]
	SAR-bisPSMA	Diagnostic in BCR PCa	AMPLIFY			[Progress bar with US flag]	[Progress bar with AU and US flags]	
	SAR-BBN	Diagnostic in BCR PCa	SABRE			[Progress bar with US flag]	[Progress bar with US flag]	
	SAR-BBN	Theranostic mCRPC	COMBAT			[Progress bar with US flag]	[Progress bar with US flag]	
Neuroblastoma	SARTATE	Theranostic	CL04			[Progress bar with US flag]	[Progress bar with US flag]	
NETs	SARTATE	Diagnostic	DISC			[Progress bar with AU and US flags]		[Progress bar with US flag]
SAR Discovery Platform	Ac-225 bisPSMA	Theranostic				[Progress bar with AU and US flags]		
	TCT and I/O combination	Theranostic				[Progress bar with AU and US flags]		
	Pan-cancer TCT	Theranostic				[Progress bar with AU and US flags]		
	Multiple novel TCTs	Theranostic				[Progress bar with AU and US flags]		

Current progress

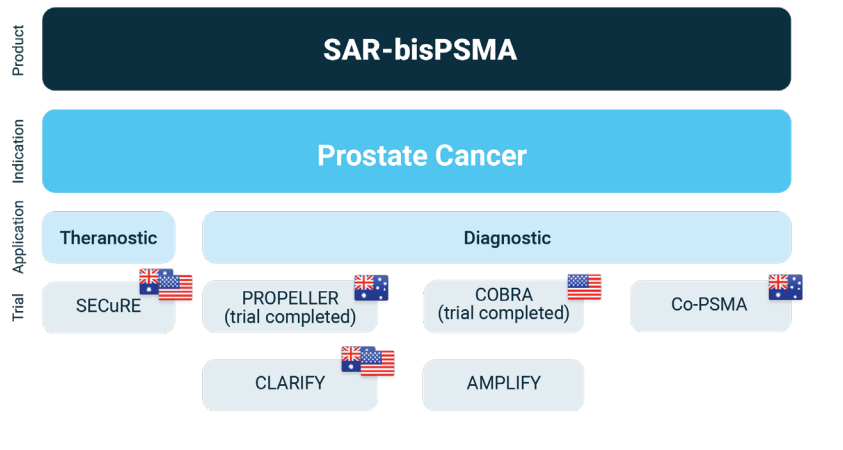
12 month progress

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

All U.S. studies are conducted under Investigational New Drug Applications

# SAR-bisPSMA

Targets the Prostate Specific Membrane Antigen (PSMA), present in the majority of prostate cancers



## Co-PSMA - Phase II Investigator-Initiated Trial (IIT)

- Led by Prof Louise Emmett at St Vincent's Hospital Sydney
- Evaluates the performance of <sup>64</sup>Cu-SAR-bisPSMA in comparison to standard-of-care <sup>68</sup>Ga-PSMA-11 product for the detection of prostate cancer recurrence
- First patient first visit expected soon

## SECuRE - Phase I/IIa



- Cohort 4 ongoing - 2 therapy cycles (12GBq)
- No DLTs observed to date
- First 3 participants in Cohort 4 had reductions in prostate-specific antigen (PSA) levels following 2 doses of 12GBq of <sup>67</sup>Cu-SAR-bisPSMA, with the largest drop being 98% to date

## CLARIFY - Phase III



- Registrational Phase III imaging trial of participants with high-risk prostate cancer prior to radical prostatectomy using <sup>64</sup>Cu-SAR-bisPSMA
- Fast-Track Designation granted by the U.S. FDA
- Recruitment ongoing

## COBRA - Phase I/II



- Positive results released with data used to support the End of Phase meeting with the U.S. FDA
- COBRA abstract selected as a Top-Rated Oral Presentation at EANM 2024 Congress

## AMPLIFY - Phase III



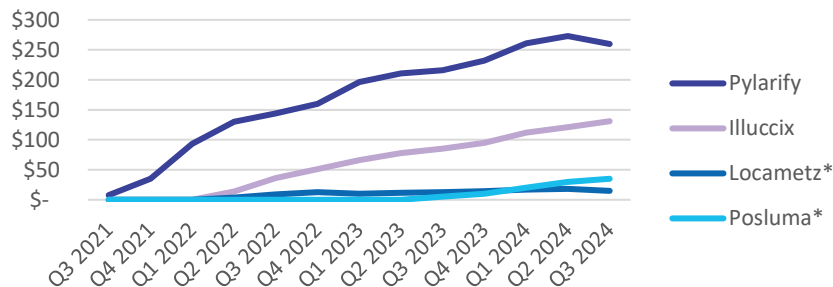
- Registrational Phase III imaging trial with <sup>64</sup>Cu-SAR-bisPSMA in prostate cancer patients with biochemical recurrence (BCR)
- Recruitment will commence early 2025

# SAR-bisPSMA market opportunity

## PSMA based diagnostics

- Current U.S. patient pool for PSMA-PET imaging is **~400k** scans per year between initial staging, suspected recurrence and patient selection for targeted therapy
- At US\$5,000 per patient dose this represents a U.S. market potential of **~US\$2Bn/year**
- By 2030 this is expected to grow to **>700k** scans per year, representing a U.S. market potential of **>US\$3Bn/year**
- 2025 CMS reimbursement changes favour the long-term potential of the best-in-class PSMA PET agent

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



\*Locametz & Posluma sales are estimations

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

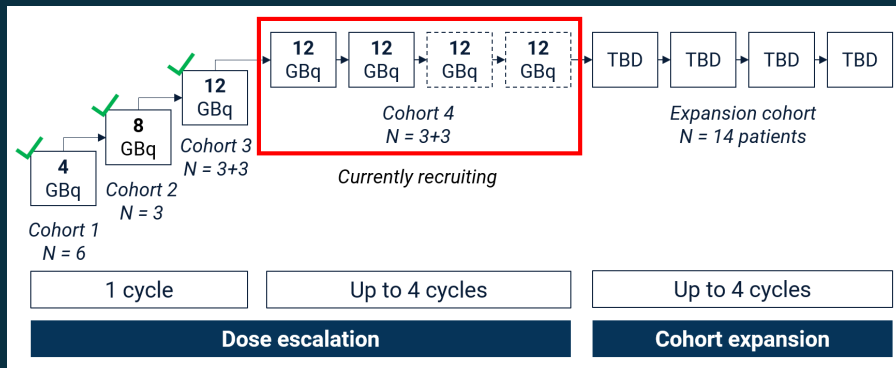
## PSMA based therapy (mCRPC)

- Current U.S. market opportunity (post chemo): **>US\$5Bn**
- Future U.S. market opportunity (including pre-chemo): **>US\$10Bn**
- Pluvicto reached blockbuster status in Q3 2024 with sales exceeding **US\$1Bn**

# Therapy program with $^{67}\text{Cu}$ -SAR-bisPSMA

## 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



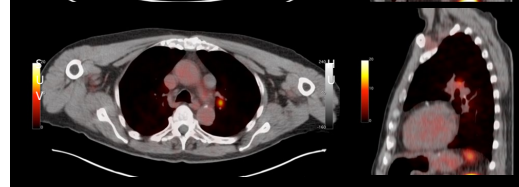
## Trial highlights to date

- Cohort 3 completed, now progressing the final 3 patients in cohort 4 at 12GBq (Pluvicto dose capped at 7.4GBq)
- First 3 participants in Cohort 4 had reductions in prostate-specific antigen (PSA) levels following 2 doses of 12GBq of  $^{67}\text{Cu}$ -SAR-bisPSMA, with the largest drop being 98% to date
- No DLTs have been observed to date
- Cohort 4 will be followed by a cohort expansion phase of the trial, pending safety evaluation

Before single cycle (8GBq)  
24 May 2023

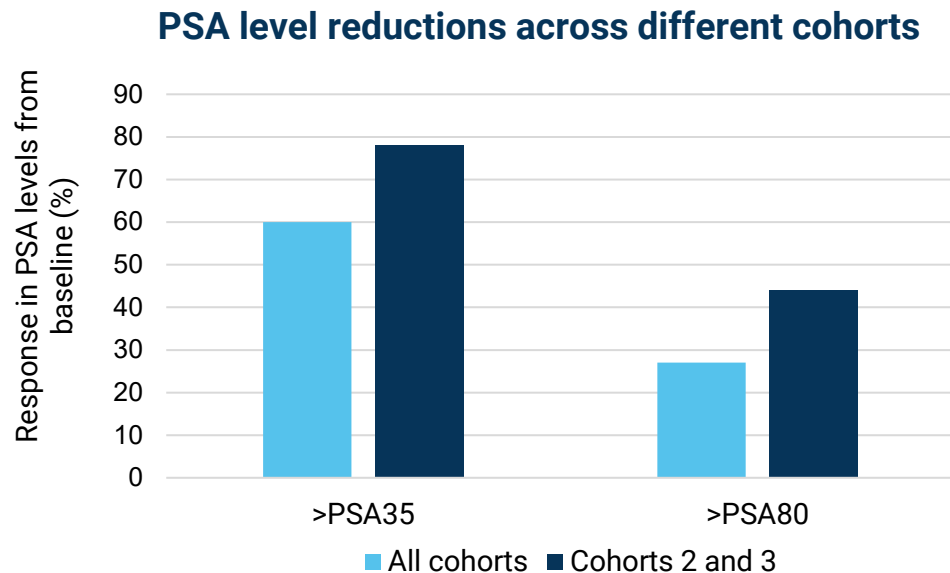


After treatment  
10 Aug 2023





# <sup>67</sup>Cu-SAR-bisPSMA single dose leads to PSA reductions in heavily pre-treated mCRPC patients



**78%**

of patients showed reductions in PSA levels >35% (cohorts 2 and 3)

**44%**

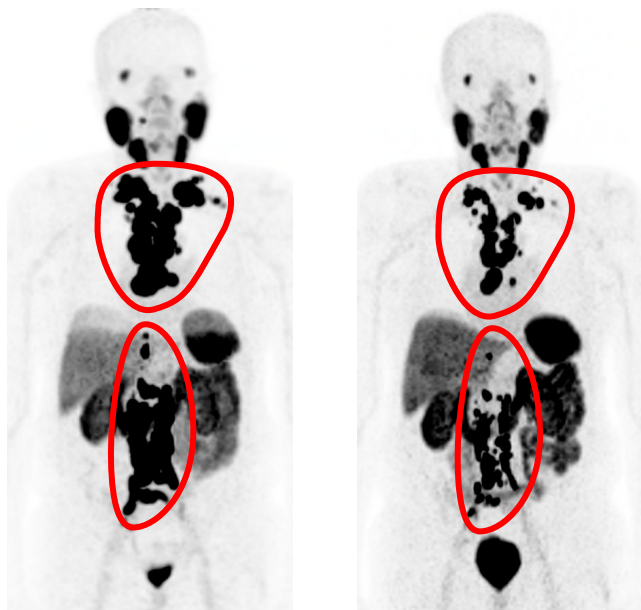
of patients showed reductions in PSA levels >80% (cohorts 2 and 3)

PSA reductions shown as the response observed post-single dose of <sup>67</sup>Cu-SAR-bisPSMA. PSA pre-dose value represents the most recent test result prior to the administration of <sup>67</sup>Cu-SAR-bisPSMA. At study entry, patients had median PSA of 117.1 ng/ml.

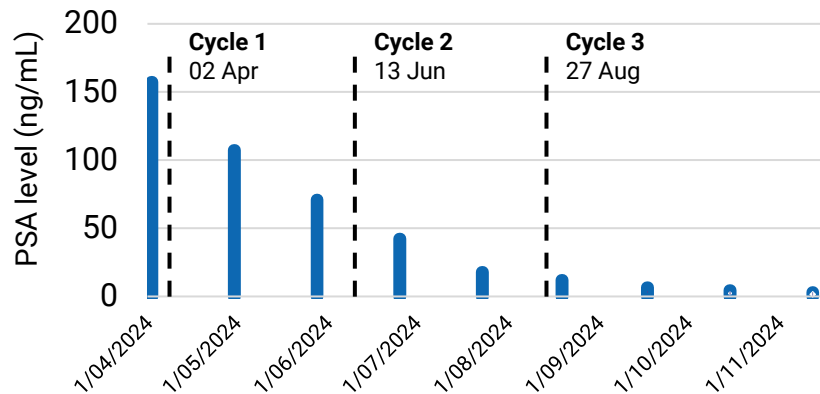
# Radiographic partial response and PSA80 following 2 cycles of $^{67}\text{Cu}$ -SAR-bisPSMA (12GBq)

Pre- $^{67}\text{Cu}$ -SAR-bisPSMA

Post-cycle 2 of  $^{67}\text{Cu}$ -SAR-bisPSMA



## PSA reduction following 3 cycles of $^{67}\text{Cu}$ -SAR-bisPSMA



**rPR**

61% tumour volume reduction following 2 cycles

**↓ 98%**

PSA reduction following 3 cycles

mCRPC patient from cohort 4 showing extensive metastasis to the lymph nodes (regions highlighted by the red lines, images on the left).  $^{64}\text{Cu}$ -SAR-bisPSMA images show reduction in tumour volume from pre- to post-treatment with  $^{67}\text{Cu}$ -SAR-bisPSMA (2 cycles, 12GBq). rPR: radiographic partial response by RECIST v1.1 assessment. PSA reduction: nadir not reached (from 157.4 to 3.2 ng/mL). Images shown as maximum intensity projections. Data cut-off 15 Nov 2024.

# <sup>67</sup>Cu-SAR-bisPSMA has a favourable safety profile

Cohorts 1-3 Adverse event (AE)	Grade 3 N = 15 (100%)
Any drug-related AEs	3 (20)
<b><i>Occurring in at least 1 participant</i></b>	
Anaemia	2 (13)
Thrombocytopenia	1 (7)
Leukopenia	1 (7)
Lymphopenia	1 (7)

**Demographics summary:** all participants had mCRPC at study entry. Median number of lines of therapy prior to receiving <sup>67</sup>Cu-SAR-bisPSMA: 4 (range 2-6). Previous treatments included ADT, ARPI, investigational agents, chemotherapy (67%, 10/15) and other radioligand therapies. Median PSA at study entry: 117.1 ng/ml (range 0.11-1,494.2).

**Cohorts 1-3 (single dose):** most adverse events (AEs) were lower Grade, with only 3/15 patients developing Grade 3 AEs (no Grade 4/5)

- No AEs were related to <sup>64</sup>Cu-SAR-bisPSMA
- AEs were reported as related to <sup>67</sup>Cu-SAR-bisPSMA in 8 out of the 15 trial participants (all Grades)
- Most AEs related to <sup>67</sup>Cu-SAR-bisPSMA were Grade 1 or 2
- No Grade 4 or 5 AEs were reported in the study

**Cohort 4 (multi-dose):** almost all AEs were mild or moderate (majority either resolved or improved at the last assessment). No DLTs observed.

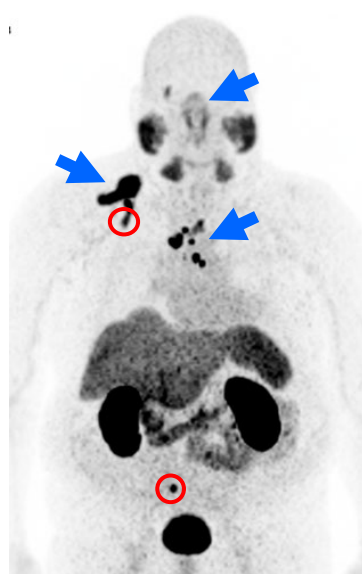
# $^{67}\text{Cu}$ -SAR-bisPSMA adaptive dosing leads to durable PSA response and disease control: EAP case report 1

Pre- $^{67}\text{Cu}$ -SAR-bisPSMA

Post- $^{67}\text{Cu}$ -SAR-bisPSMA  
(4 cycles x 4GBq)

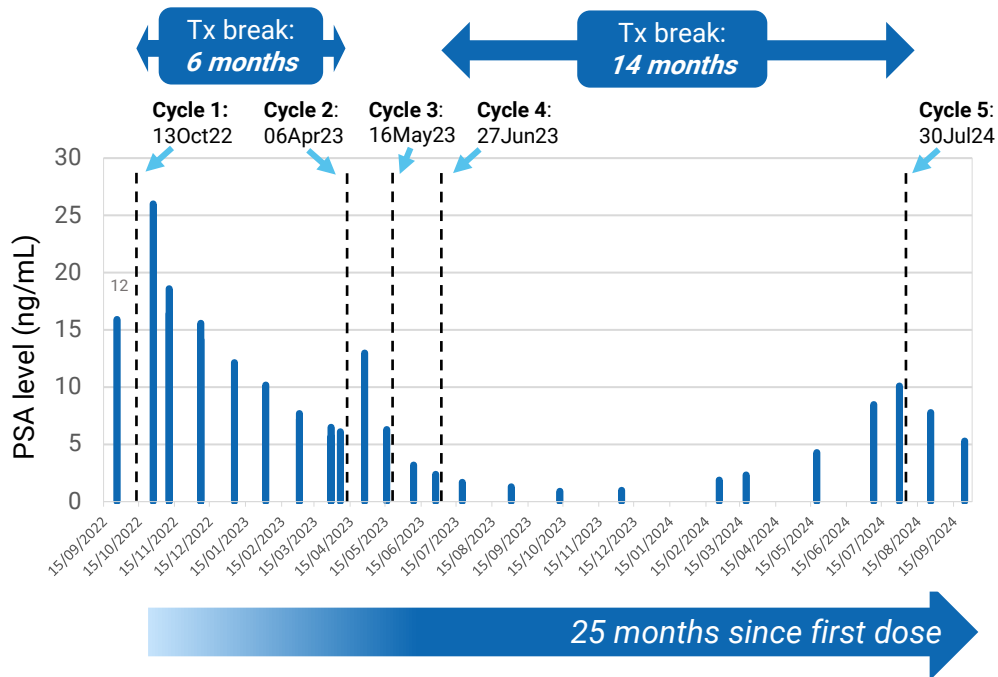


05 Oct 2022  
(baseline)



24 Jul 2024 (14 months after the  
4<sup>th</sup> dose of  $^{67}\text{Cu}$ -SAR-bisPSMA)

## PSA reduction following multi-doses of $^{67}\text{Cu}$ -SAR-bisPSMA



mCRPC patient with metastasis to the bones (blue arrows, images). Definitive radiation therapy in 2013. Previous systemic therapies: ADT, 2 ARPIs. Images show reduction in lesion uptake ( $^{67}\text{Cu}$ -SAR-bisPSMA PET) following 4 doses of  $^{67}\text{Cu}$ -SAR-bisPSMA (4GBq each), with reduction in PSA of 94.4%. Reduction in SUVmax and tumour volume: 72.5% and 41.6%, respectively. New bone lesions detected in latest PET (red circles, approximately 14 months post-4<sup>th</sup> dose of  $^{67}\text{Cu}$ -SAR-bisPSMA). Recent rising in PSA led to the administration of a 5<sup>th</sup> cycle of  $^{67}\text{Cu}$ -SAR-bisPSMA (8GBq). PSA reduction of 47.52% vs latest PSA peak (10.1 ng/mL; PSA continues to decline). AE related to  $^{67}\text{Cu}$ -SAR-bisPSMA: mild (Grade 1) thrombocytopenia (improving). Images: maximum intensity projection. Graph dash lines: administration of  $^{67}\text{Cu}$ -SAR-bisPSMA. EAP: Expanded Access Program. Data cut-off 28 Sep 2024.

# $^{67}\text{Cu}$ -SAR-bisPSMA adaptive dosing leads to durable complete response: EAP case report 2

- Complete **anatomical** response (CT; RECIST v1.1)
- Complete **molecular** response (PET)
- Complete **biochemical** response (undetectable PSA)

Pre- $^{67}\text{Cu}$ -SAR-bisPSMA      Post- $^{67}\text{Cu}$ -SAR-bisPSMA  
(Two cycles, 8GBq each)

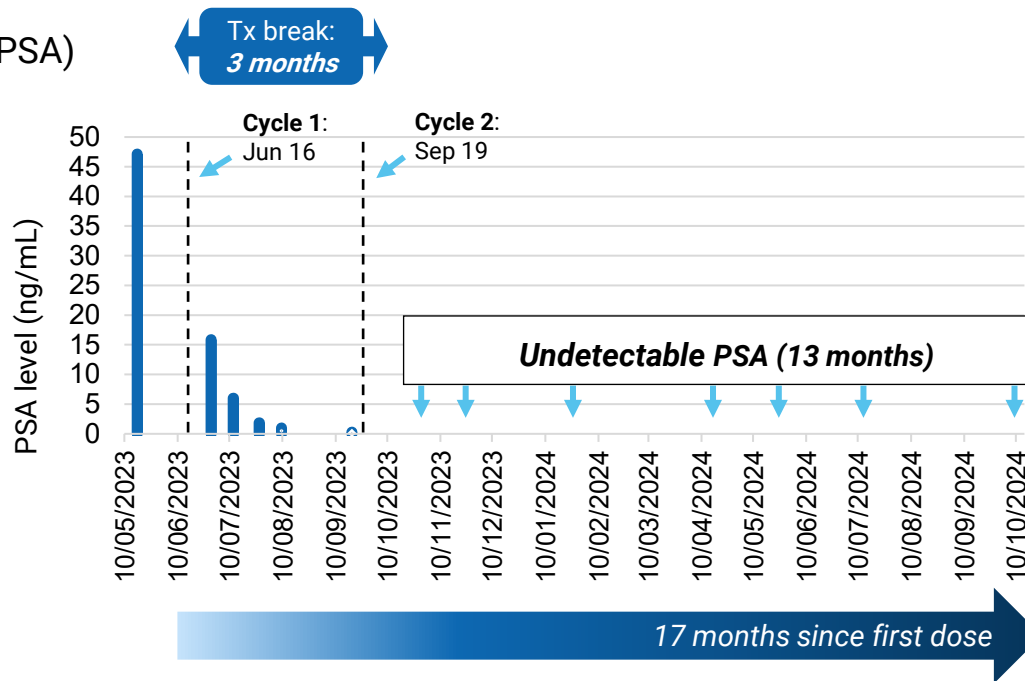


24 May 2023  
(baseline)



22 Nov 2023 (5.7 months after the  
1<sup>st</sup> dose of  $^{67}\text{Cu}$ -SAR-bisPSMA)

## PSA reduction following 2 cycles of $^{67}\text{Cu}$ -SAR-bisPSMA

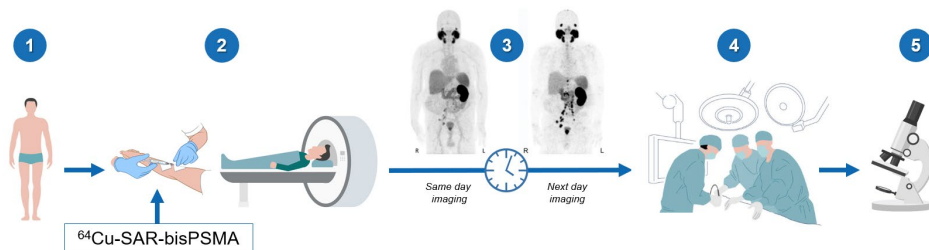


Images: PET scan showed no uptake of  $^{64}\text{Cu}$ -SAR-bisPSMA above the background level following 2 doses of  $^{67}\text{Cu}$ -SAR-bisPSMA, demonstrating a complete molecular response. Dash lines in graph: administration of  $^{67}\text{Cu}$ -SAR-bisPSMA. Safety: xerostomia (Grade 1), fatigue (Grade 2), both resolved; dysgeusia (Grade 1), improved; thrombocytopenia (Grade 1); anaemia (Grade 3, improved to Grade 2). EAP: Expanded Access Program. PSA limit of detection 0.05 ng/mL. PSA limit of detection: 0.05 ng/ml. Images: maximum intensity projection. Data cut-off 14 Oct 2024.

# Diagnostic program with $^{64}\text{Cu}$ -SAR-bisPSMA

## Trial overview

- Phase III registrational trial in high-risk prostate cancer patients prior to undergoing radical prostatectomy and pelvic lymph node dissection
- Assessing same-day and next-day imaging of  $^{64}\text{Cu}$ -SAR-bisPSMA in this patient population
- Recruitment is ongoing



1. Screening
2.  $^{64}\text{Cu}$ -SAR-bisPSMA administration followed by PET/CT scan
3. "Same day" and "next day" imaging
4. Surgical removal of the prostate and pelvic lymph nodes
5. Laboratory assessments (histopathology) to confirm the results of the PET scan

## U.S. FDA Fast Track Designation (FTD)

- U.S. FDA granted FTD for  $^{64}\text{Cu}$ -SAR-bisPSMA for PET imaging of PSMA positive prostate cancer lesions with suspected metastasis who are candidates for initial definitive therapy
- FTD is designed to expedite the development and regulatory review of novel drugs addressing serious conditions with significant unmet medical need
- Fast track products must show advantage over available therapy

## Key benefits

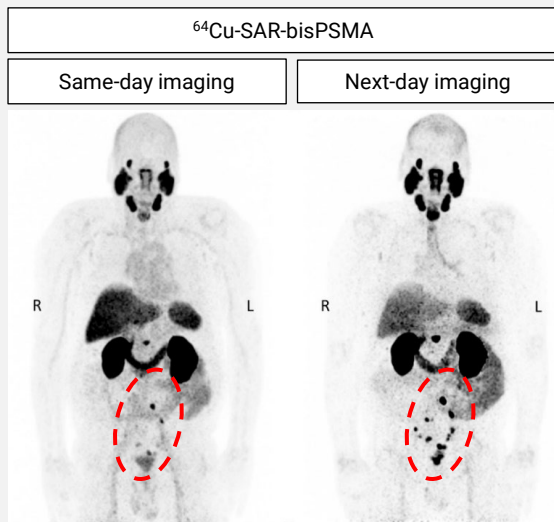
- Potentially faster product approval review process
- More frequent communication with the FDA
- Rapid query resolution
- Clarity can submit sections as they are completed rather than waiting for complete application package

# SAR-bisPSMA is safe and effective in detecting tumours in prostate cancer patients

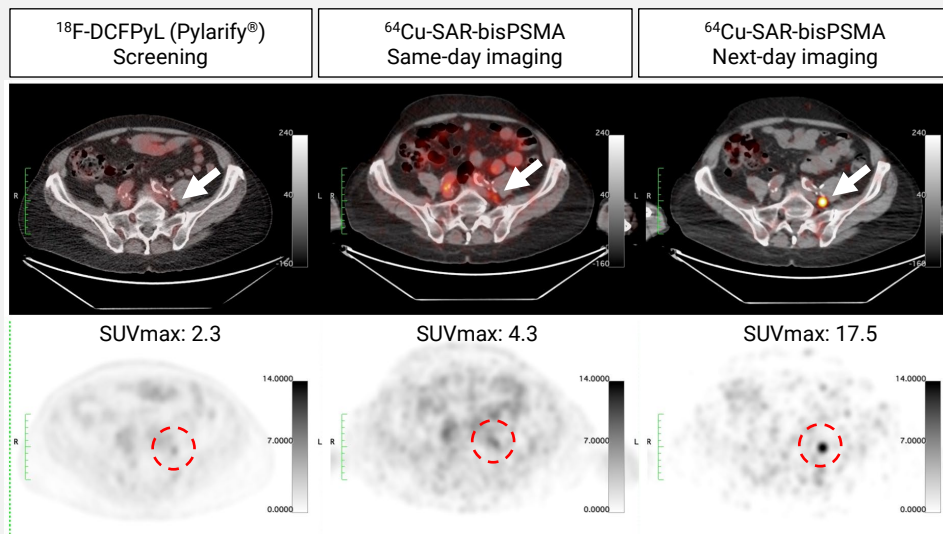
Clinicians reported they would change their treatment plan in approximately 50% of patients due to  $^{64}\text{Cu}$ -SAR-bisPSMA scans, signalling a potential material improvement in patient care

## Patients with negative/equivocal SOC scans - COBRA study (biochemical recurrence)

**82%** more lesions detected on next-day imaging (2 mm-range)

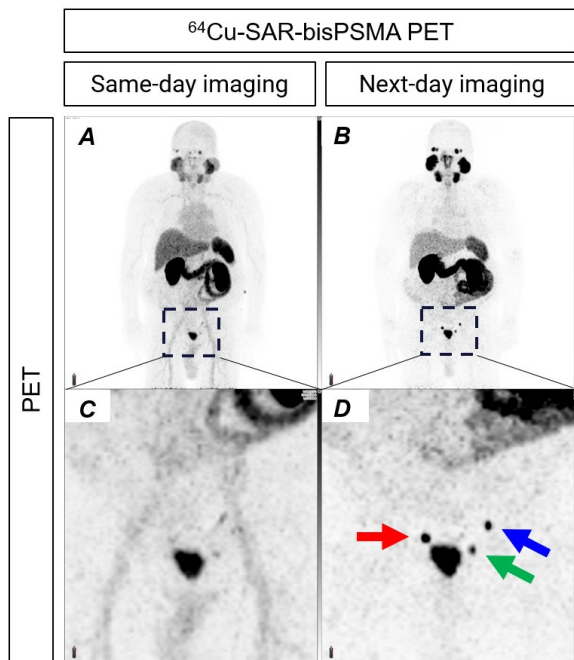


**34%** more patients with a positive scan on next-day imaging



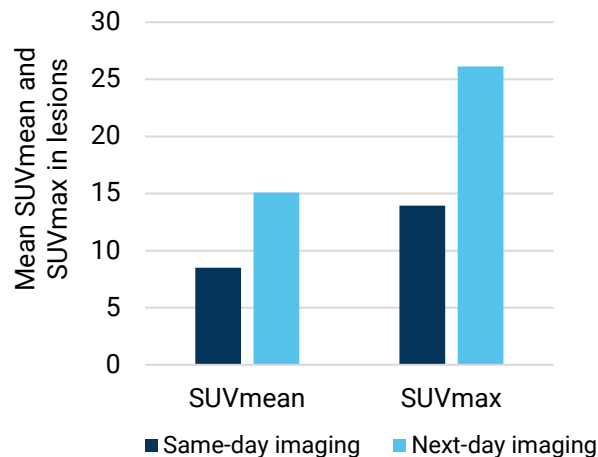
Left images. Up to 80 lesions detected on same-day imaging vs. up to 153 lesions on next-day imaging across all participants. Right images: pelvic lymph node detected by  $^{64}\text{Cu}$ -SAR-bisPSMA on next-day imaging, but not with Pylarify® at screening. Patients with a positive  $^{64}\text{Cu}$ -SAR-bisPSMA scan: from up to 58% to up to 80%, same and next-day imaging respectively). Nordquist et al., SNMMI 2024.

# Higher uptake and contrast in lesions on next-day imaging and detection of lesions in the 2mm range



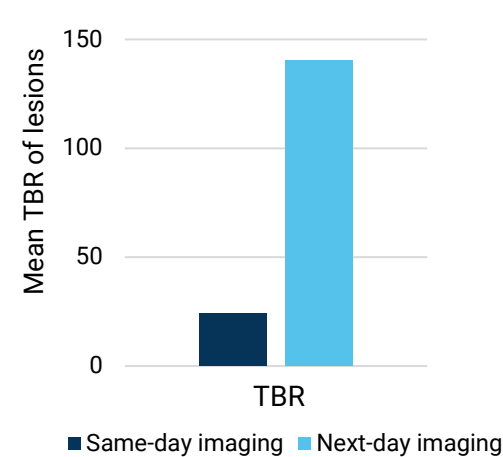
**Figure 1.** Pelvic lymph nodes showing uptake of  $^{64}\text{Cu}$ -SAR-bisPSMA on next-day imaging (arrows, B and D). Blue arrow: lesion size 3.8 mm x 4.4 mm, SUVmean 20.6, SUVmax 22.1 and TBR 130.1. Green arrow: lesion size also 3.8 mm x 4.4 mm, SUVmean 11.9, SUVmax 12.8 and TBR 75.3. Red arrow: size >5 mm. Inset in top images (A, B) displays pelvic region (bottom images, C and D).

## SUVmean and SUVmax in lesions detected by $^{64}\text{Cu}$ -SAR-bisPSMA



**>80% increase in mean SUVmean and SUVmax**  
(same-day vs. next-day imaging)

## TBR of lesions detected by $^{64}\text{Cu}$ -SAR-bisPSMA



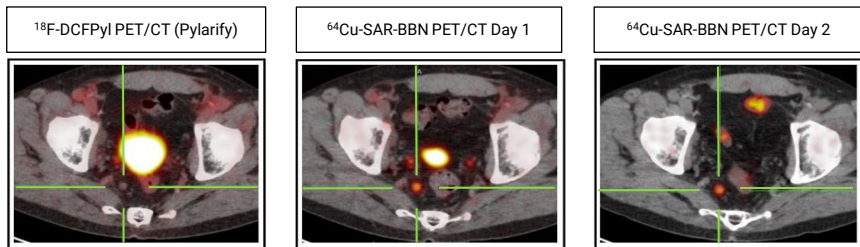
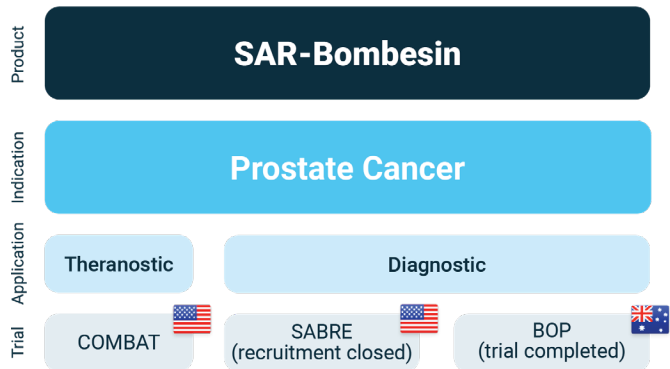
**>5x higher mean TBR**  
(same-day vs. next-day imaging)

**Figure 2.** SUVmean/max and TBR comparing same-day (Day 0) and next-day (Day 1) imaging. Average increase across 3 readers. SUVmean: mean standardised uptake value. SUVmax: maximum standardised uptake value. TBR: tumour-to-background ratio. The SUVmax, SUVmean and TBR were assessed in up to 25 lesions per patient on each  $^{64}\text{Cu}$ -SAR-bisPSMA scan. Ranges across the readers for same-day and next-day imaging, respectively: SUVmean 6.6-9.9 and 14.7-15.8; SUVmax 13.9-14.0 and 22.2-33.4; TBR 23.2-25.4 and 118.1-181.7. TBR = SUVmax of the lesions / SUVmean of the gluteus region.



# SAR-Bombesin

Targets the Gastrin Releasing Peptide receptor (GRPr), which is present in a number of cancers, including breast and prostate cancers



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

## COMBAT – Phase I/IIa therapy



- $^{64}\text{Cu}$ -SAR-BBN and  $^{67}\text{Cu}$ -SAR-BBN for identification and treatment of GRPr-expressing mCRPC in patients who are ineligible for therapy with  $^{177}\text{Lu}$ -PSMA-617
- Progressing through dose escalation across 5 sites in the U.S.
- Presented at ASCO GU (Jan 24) and SNMMI (Jun 24)

## SABRE – Phase II



- Phase II PET imaging trial of participants with PSMA-negative BCR of prostate cancer using  $^{64}\text{Cu}$ -SAR-BBN
- Follow up period completed with data review and analysis ongoing
- Initial data readout anticipated Q1 2025
- Presented at ASCO GU (Jan 24) and SNMMI (Jun 24)

## BOP – Phase II

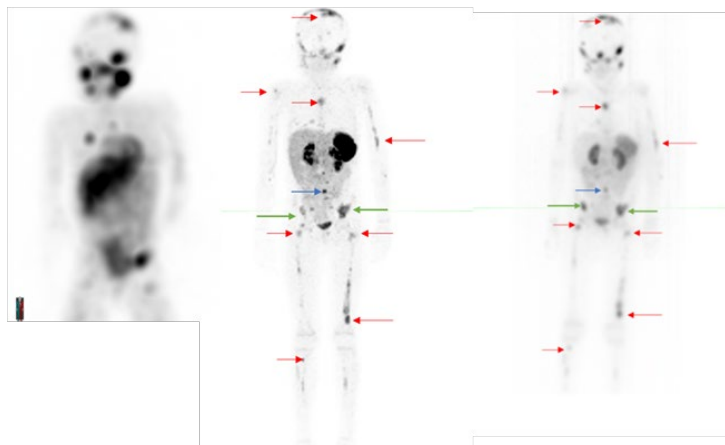
- Investigator Initiated PET imaging trial of participants with negative PSMA PET or low PSMA expression disease in patients with suspected BCR of prostate cancer and patients with mCRPC using  $^{64}\text{Cu}$ -SAR-BBN led by Prof Louise Emmett at St Vincent's Hospital Sydney
- Manuscript published in the Journal of Nuclear Medicine (Aug 2024)

# SARTATE

Targets the Somatostatin Receptor 2 (SSTR2), which is present in an aggressive childhood cancer, neuroblastoma, as well as neuroendocrine tumours (NETs), among other cancers

High Accuracy

High Precision



$^{123}\text{I}$  MIBG  
Current Standard  
of Care

$^{64}\text{Cu}$  SARTATE™  
PET screening  
4 hours

$^{67}\text{Cu}$  SARTATE™  
SPECT scan  
24 hours

(in the same patient)

## SARTATE

Neuroblastoma

NETs

Theranostic

Diagnostic

CL04

DISCO  
(recruitment closed)

### CL04 – Phase I/IIa

- $^{64}\text{Cu}/^{67}\text{Cu}$ -SARTATE theranostic clinical trial in high-risk neuroblastoma
- Cohort 4 recently completed. Update provided shortly.

### DISCO – Phase II

- A diagnostic imaging study of  $^{64}\text{Cu}$ -SARTATE using PET on patients with known or suspected NETs
- Recruitment closed with final patients soon to complete the follow-up period
- Initial data readout anticipated mid 2025



# Scaling manufacturing for commercial launch

Clarity continues to strengthen and expand its manufacturing and supply chain footprint, creating additional capacity and flexibility to supply products to any state in the U.S. for upcoming and ongoing late-stage clinical trials



Clinical Supply Agreement for  $^{67}\text{Cu}$ -SAR-bisPSMA

Large-scale manufacturing of copper-67 isotope and cGMP  $^{67}\text{Cu}$ -SAR-bisPSMA drug product in the U.S. under one roof



Drug manufacturing of  $^{67}\text{Cu}$ -SAR-bisPSMA

Manufacturing the  $^{67}\text{Cu}$ -SAR-bisPSMA drug product at Nucleus RadioPharma's state-of-the-art facility in Rochester, MN



Supply Agreement for the production of Cu-64

The first private supplier of Cu-64 to join Clarity's network in the U.S., which will support the Company as it progresses towards commercial launch



Actinium-225 program

Supply of therapeutic alpha-emitting actinium-225 for Clarity's Targeted Alpha-particle Therapy (TAT) program with bisPSMA

# Highly experienced team



Dr Alan Taylor  
Executive Chairman



Michelle Parker  
CEO



Dr Colin Biggin  
COO



Eva Lengyelova  
EVP – Clinical Development



Shaemus Gleason  
EVP - Operations



Dr Othon Gervasio  
Chief Medical Officer



Dr Matt Harris  
Chief Technology Officer



Mary Bennett  
Head of People and Culture



Robert Vickery  
Company Secretary



Kathryn Williams-Day  
VP - Regulatory Affairs  
and Quality



David Green  
Chief Financial Officer



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

- Development, approval and launch of 1<sup>st</sup> approved radiopharmaceutical therapy product for prostate cancer (Xofigo)
- Decades of experience spanning across science, nuclear medicine/PET and pharmaceutical industries
- Investment banking experience focused on the life sciences sector

# Thank you



## Contact details

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