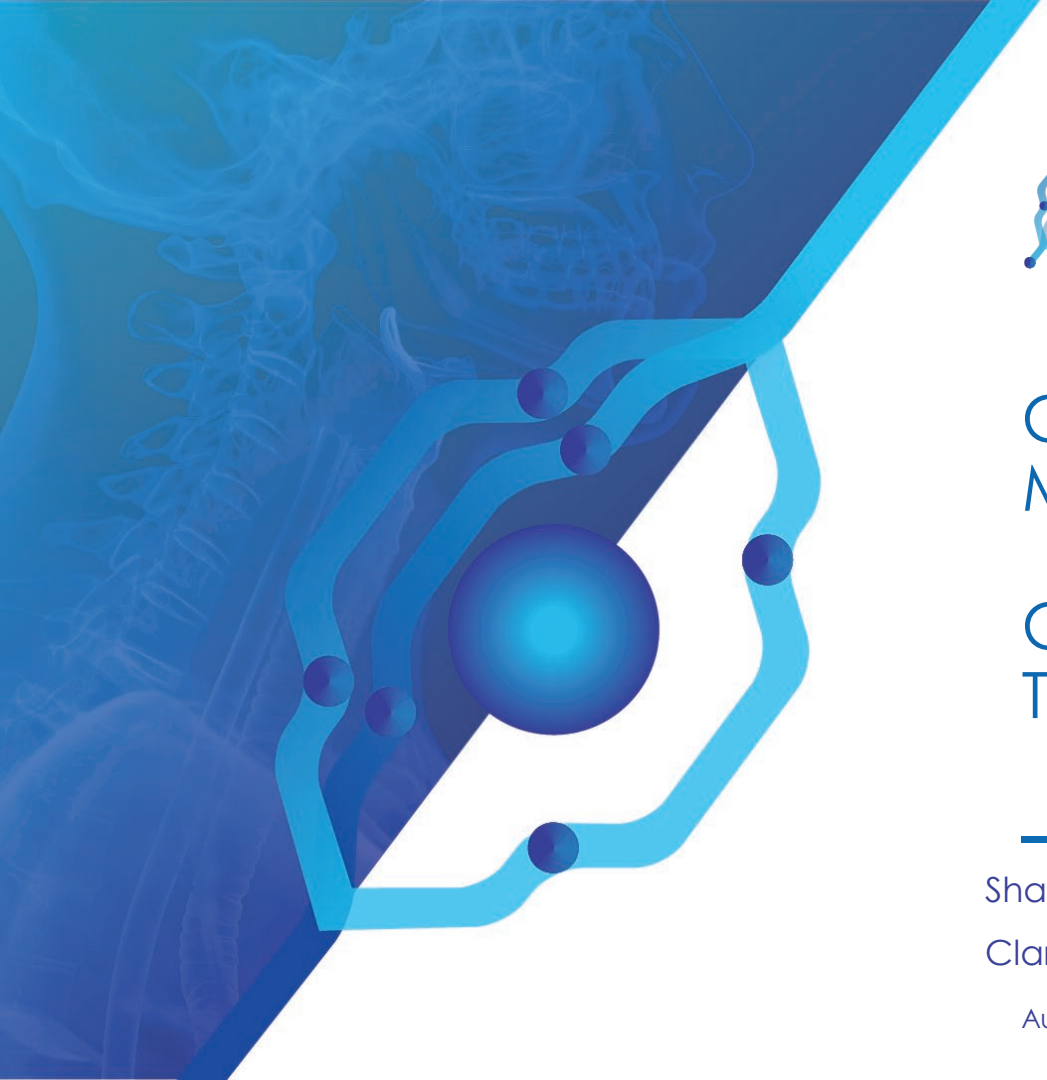


CLARITY
PHARMACEUTICALS

Cu-67 Users Group Meeting

Clarity's Targeted Copper Theranostics (TCT)platform

Shaemus Gleason, EVP US Operations

Clarity Pharmaceuticals

August 2021

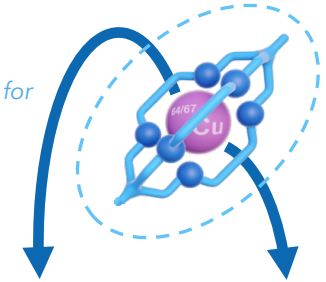
Overview

Clarity Pharmaceuticals (the "Company") is a clinical stage radiopharmaceutical company developing next-generation products to address the growing need for radiopharmaceuticals in oncology

- Global leader in Targeted Copper Theranostics (TCT)
- Proprietary SAR Technology platform employs a superior chelator ("cage") for copper used in the diagnosis and treatment of a wide range of cancers
- Diverse range of assets in clinical trials across a range of children and adult cancers
- Broad portfolio of patent families across platform, pipeline and products
- Strong focus on US regulatory pathway: two Investigational New Drugs (INDs) in place and two Rare Paediatric Disease Designations (RPDD) awarded, which may potentially give Clarity access to two Priority Review Vouchers (PRV)
- Highly experienced team with extremely successful track record in radiopharmaceutical development
- Superior commercialisation potential enabled by properties, manufacturing and supply of copper radioisotopes

SAR Technology Platform

Superior chelator ("cage") for copper radioisotopes



Targeted Copper Theranostics ("TCT")

Clarity uses a "perfect pair" of copper radioisotopes

Copper-64 (Diagnostic) ^{64}Cu **OR** ^{67}Cu ***Copper-67 (Therapy)***

…the foundation for Clarity's product portfolio

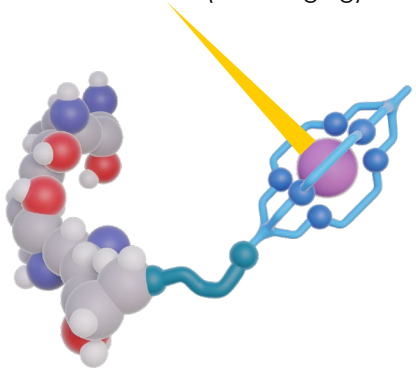
SARTATE™		SAR-Bombesin Pan cancer (e.g. breast and prostate cancers)	SAR-bisPSMA Prostate cancer
Neuroblastoma (NB)	Neuroendocrine Tumours (NETs)		
Theranostic	Diagnostic	Theranostic	Theranostic

Theranostics in practice

Theranostic approach increases the probability of treatment success by selecting patients that demonstrate uptake of the diagnostic agents to visualise their cancer prior to therapy

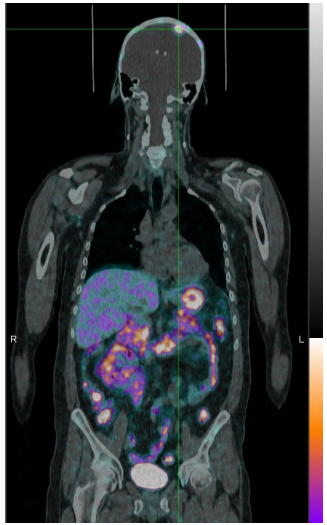
DIAGNOSIS (Copper-64)

Positron emission (PET imaging)



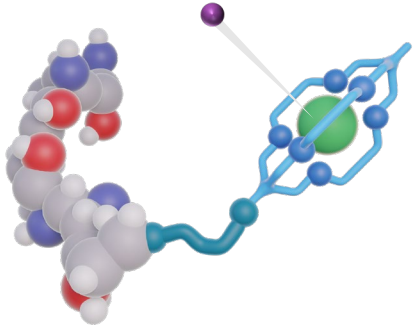
Diagnostic products use positron emitting radionuclides, such as ^{64}Cu, which are detected by Position Emission Tomography (PET) cameras

Patients are imaged with a PET camera, which allows clinicians to identify the location of the tumours and select only those patients for Copper-67 therapy that demonstrate uptake of the product in the tumours



THERAPY (Copper-67)

Beta (β^-) particle emission



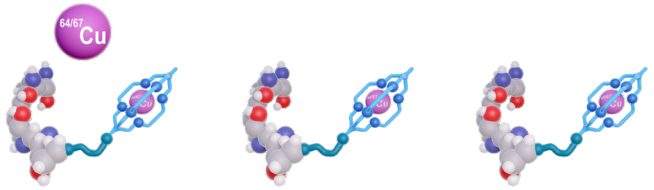
Therapeutic products use beta (β^-) particle emitting radioisotopes such as ^{67}Cu, which kill cancer cells by destroying their DNA

Clarity's best-in-class chelator

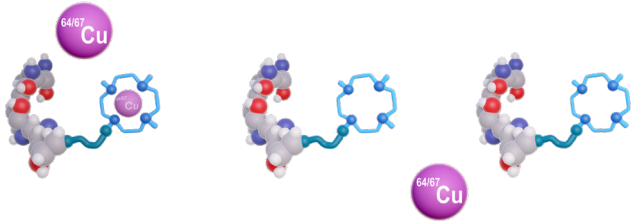
Until now, the utilisation of copper radioisotopes has been hampered by the inability to hold the isotopes in a suitable cage – Clarity's chelator addressed this issue

Chelator comparison

Clarity's SAR Technology holds copper securely

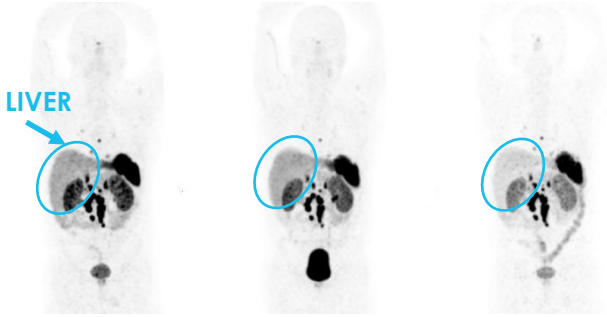


Other chelators leak copper



- Stable products are a key criteria in drug development
- Clarity's chelator securely holds copper when in the body, enabling better diagnostic and therapeutic outcomes
- Other chelators leak copper, which leads to suboptimal clinical outcomes and a lower level of safety

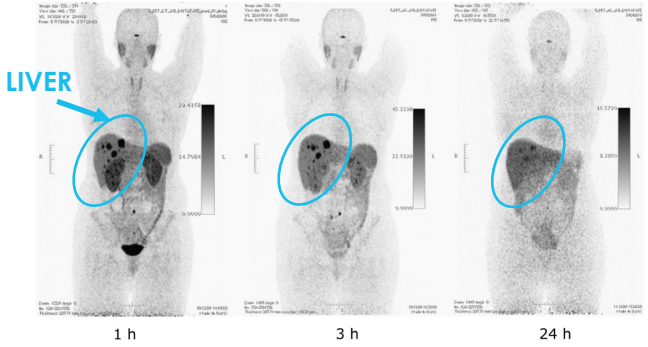
^{64}Cu SARTATE™



- Minimal free ^{64}Cu in the liver (copper is not leaking from the product)
- Excellent early and late retention of ^{64}Cu SARTATE™ in known tumours

Image: Hicks et al. J Nucl Med 2019; 60:777-785

^{64}Cu DOTATATE



- Increase in background in the liver indicative of free ^{64}Cu (copper leaking from the product)
- Poor late retention of ^{64}Cu DOTATATE in known tumours

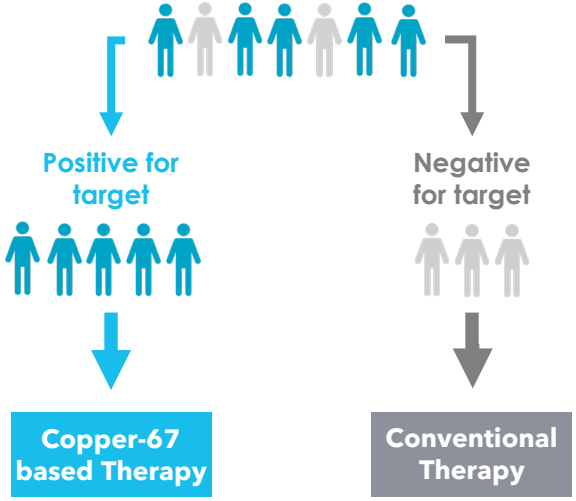
Image: Pfeifer et al. J Nucl Med 2012; 53:1207-15

Clinical benefits of the copper isotope "perfect pair"

Highest Accuracy

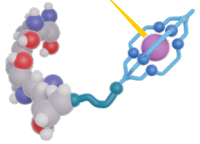
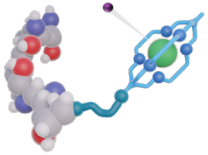
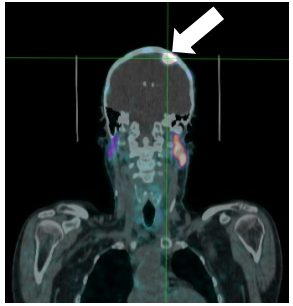
Achieved by only treating those patients who show product uptake in the tumour in the diagnostic PET scan

Copper-64 based diagnostic imaging scan



Highest Precision

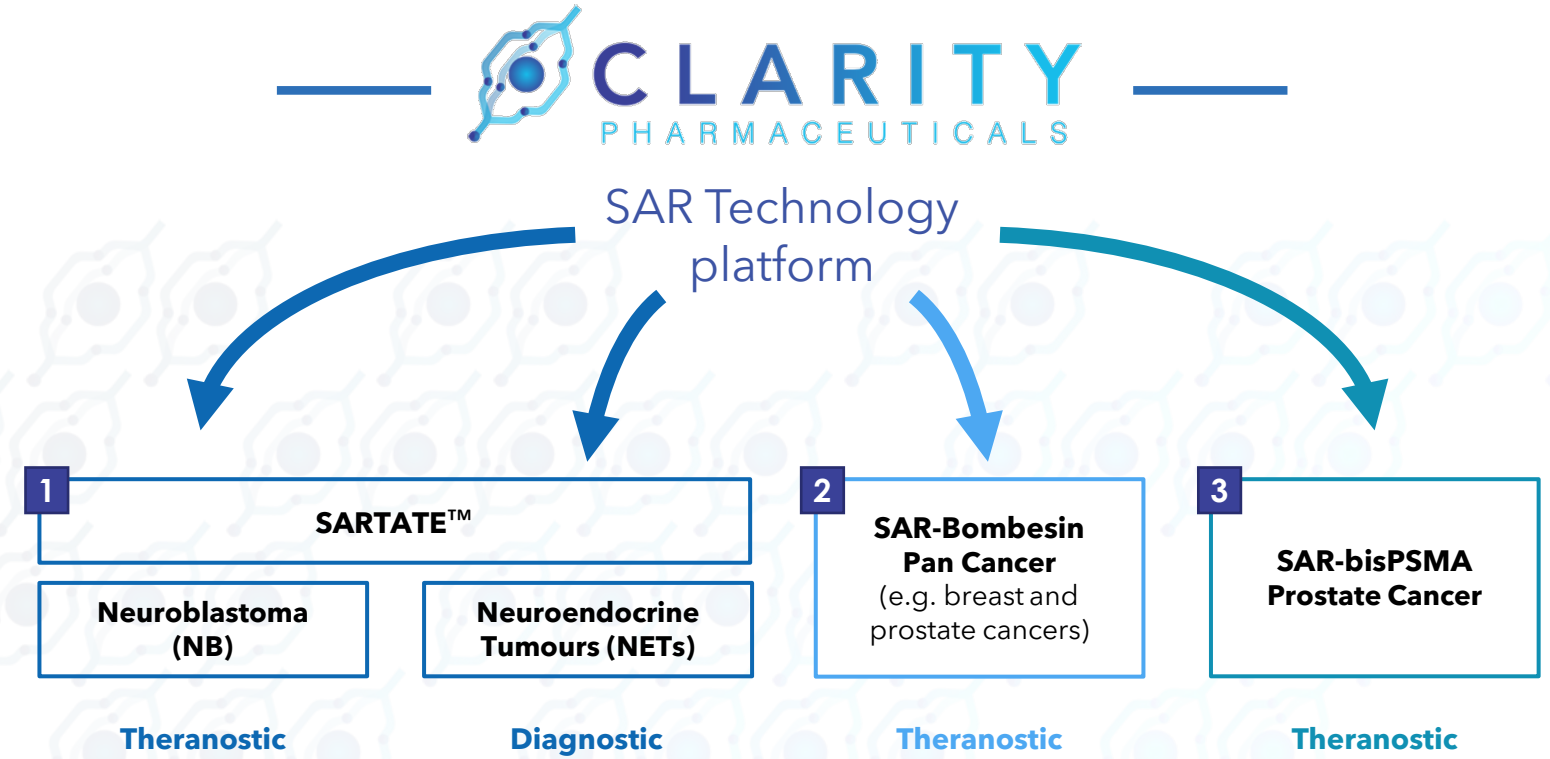
Achieved by using of the same targeting molecule with the same chemical element inside the chelator

Diagnostic	Therapeutic
^{64}Cu SARTATE™	^{67}Cu SARTATE™
 Positron emission (PET imaging) for diagnosis	 Beta particle (β^-) emission for therapy
Clinical Evidence	
^{64}Cu SARTATE™ PET/CT Screening	^{67}Cu SARTATE™ 24 hour SPECT/CT
	

The diagnostic and therapeutic product localise to exactly the same tumour (white arrow) in this patient with a brain tumour (meningioma).

Ref. Bailey et al., (2019); Schembri et al., (2019)

Clarity's clinical products



SARTATE™ CL04: $^{64/67}$Cu SARTATE™

Theranostic trial in neuroblastoma

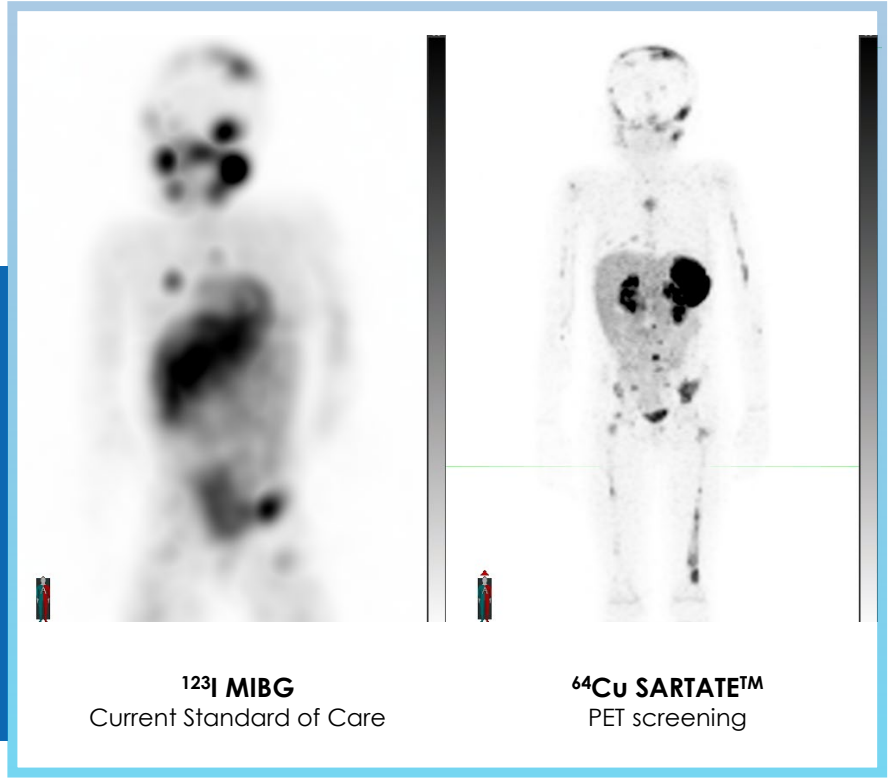
Phase I/IIa

- Dose escalation/expansion over multiple doses of therapy to paediatric patients with high-risk neuroblastoma (NCT 04023331)
- Trial status: Recruiting at Memorial Sloan Kettering Cancer Center and 3 additional U.S. clinical sites.

Neuroblastoma is one of the most aggressive childhood cancers

- Each year, there are around 800 new cases of Neuroblastoma registered in the US
- Neuroblastoma is the most common cancer to be diagnosed in the first year of life and accounts for around 15% of paediatric cancer mortality
- Approximately 84% of neuroblastomas express SSTR2

Highest Accuracy



^{123}I MIBG
Current Standard of Care

^{64}Cu SARTATE™
PET screening

SARTATE™ CL04: $^{64/67}$Cu SARTATE™

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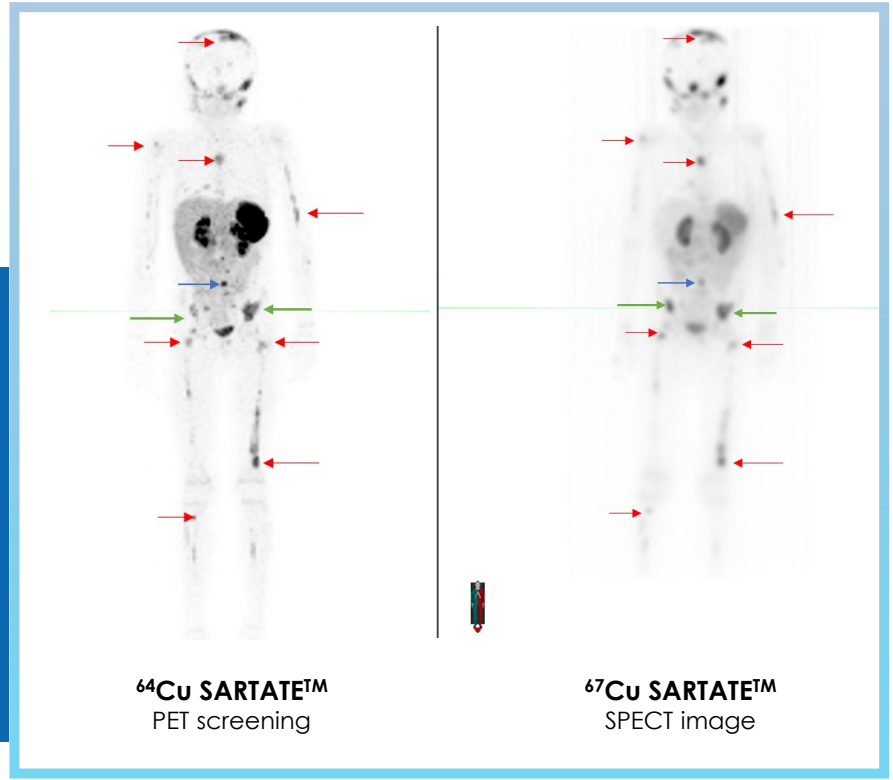


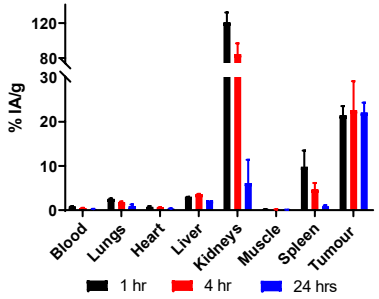
^{64}Cu SARTATE™
PET screening

^{67}Cu SARTATE™
SPECT image

SAR-bisPSMA: Prostate cancer

SAR-bisPSMA has ideal product characteristics for a radiopharmaceutical

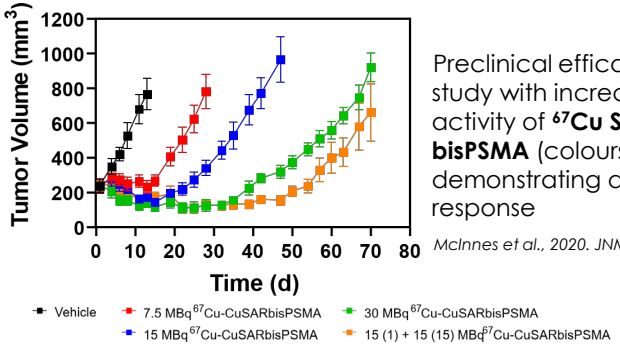
High uptake and retention in tumour



Preclinical biodistribution study demonstrating high uptake and retention of **^{64}Cu SAR-bisPSMA** in tumours with rapid clearance from non-target organs

Zia et al., 2019. Ang.Chem

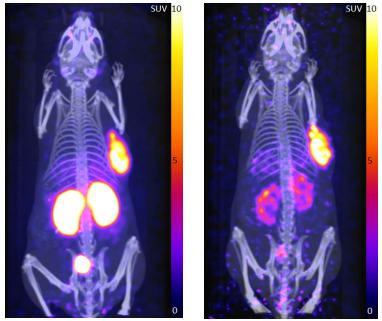
Significant anti-tumour effect



Preclinical efficacy study with increasing activity of **^{67}Cu SAR-bisPSMA** (colours) demonstrating dose response

McInnes et al., 2020. JNM

Rapid kidney clearance of non-bound activity



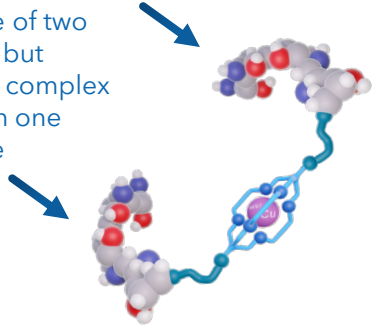
1 hr 24 hr

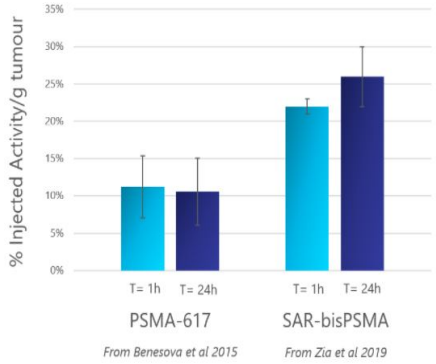
Tumour targeting and superior retention over 24 hours

PET images showing **^{64}Cu SAR-bisPSMA** targeting to tumours over time and rapid kidney clearance

'Bis-PSMA'

The term Bis is used to denote the presence of two identical but separate complex groups in one molecule





SAR-bisPSMA: SECuRE & Propeller

SECuRE

SECuRE: Systemic Copper theranostics in prostate cancer (NCT04868604)

A Phase I/IIa study of ^{64}Cu SAR-bisPSMA and ^{67}Cu SAR-bisPSMA for identification and treatment of PSMA-expressing metastatic castrate resistant prostate cancer (mCRPC)

- Theranostic multi-centre, single arm, dose escalation study with a cohort expansion planned for up to 44 patients
- Open IND with the US FDA for ^{64}Cu SAR-bisPSMA and ^{67}Cu SAR-bisPSMA
- The trial employs diagnostic PET imaging with ^{64}Cu SAR-bisPSMA for selection of patients suitable for therapy cycles with ^{67}Cu SAR-bisPSMA
- Trial recruiting

PROPELLER

PROPELLER: PET Imaging of Participants With Confirmed Prostate Cancer (NCT04839367)

A Phase I multi-centre, blinded review, dose ranging, non-randomised study in 30 patients across Australia

- The aim of the PROPELLER study is to:
- Determine the safety and tolerability of ^{64}Cu SAR-bisPSMA in participants with untreated, confirmed prostate cancer and planned for radical prostatectomy
- Compare ^{64}Cu SAR-bisPSMA to ^{68}Ga PSMA-11, the Standard of Care for prostate cancer imaging in Australia
- Trial recruiting

Supply and manufacturing advantages of copper

The supply and manufacturing process of copper radioisotopes gives Clarity's theranostic products an advantage in the commercialisation phase, enabling an efficient and streamlined distribution model

Copper-64 (^{64}Cu)

Isotope production

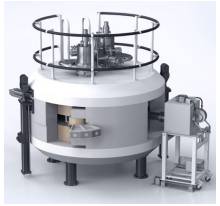
- Hundreds of patient doses can be produced daily on a single cyclotron
- A small number of cyclotrons can cover national/regional needs for commercial products

Logistics

- 12.7 hour half life of ^{64}Cu facilitates central manufacture of final drug products and overnight shipment to treatment centres
- Diagnostic drug products have a shelf life of ~48 hours (compared to 4 h for ^{68}Ga based products)

End users

- Product on demand in required volume
- Flexibility for in time of administration and scanning yet fits into established patient flow at clinic
- Provides the option to re-image the patient at later time points



Copper-67 (^{67}Cu)

Isotope production

- High purity Cu-67 produced in the US on electron accelerators
- Product supply agreements to supply the US at sufficient scale and suitable price point for later stage clinical trials and commercialsation
- Increasing capabilities in other territories is relatively low cost

Logistics

- 2.6 day half life facilitates central manufacture of final drug products and overnight shipment to end users

End users

- No long-lived radioactive contaminants/waste issues
- Reliable product unaffected by reactor outages
- Domestic US supply in sufficient scale and volume to permit roll out into multiple indications

- Significant manufacturing synergies by using same isotopes of copper across the SAR technology platform
- Readily available and low-cost stable isotopes for production (^{64}Ni for ^{64}Cu and ^{68}Zn for ^{67}Cu)
- Currently, no known competition for existing supply