ASX MEDIA RELEASE

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Clarity's theranostic prostate cancer trial advances to cohort 2

Highlights

- **Cohort 1 of the SECuRE trial has been completed in 6 participants with metastatic castrate-resistant prostate cancer (mCRPC) who received therapy with ^{67}Cu SAR-bisPSMA at the lowest dose level of 4GBq.**
- **No dose limiting toxicities (DLTs) have been reported in cohort 1.**
- **The Safety Review Committee (SRC) has recommended that the trial continues to cohort 2.**
- **Recruitment has opened at clinical sites in the United States (US) at the cohort 2 dose level of 8GBq and patients are currently in screening for all available slots.**
- **Additional therapy cycles of ^{67}Cu SAR-bisPSMA have been requested by clinicians under the US Food and Drug Administration (FDA) Expanded Access Program (EAP).**
- **Early data from the EAP indicates positive effects of the lowest dose of ^{67}Cu SAR-bisPSMA on lesions, demonstrated by SPECT-CT images, with reduction in Prostate Specific Antigen (PSA) levels.**

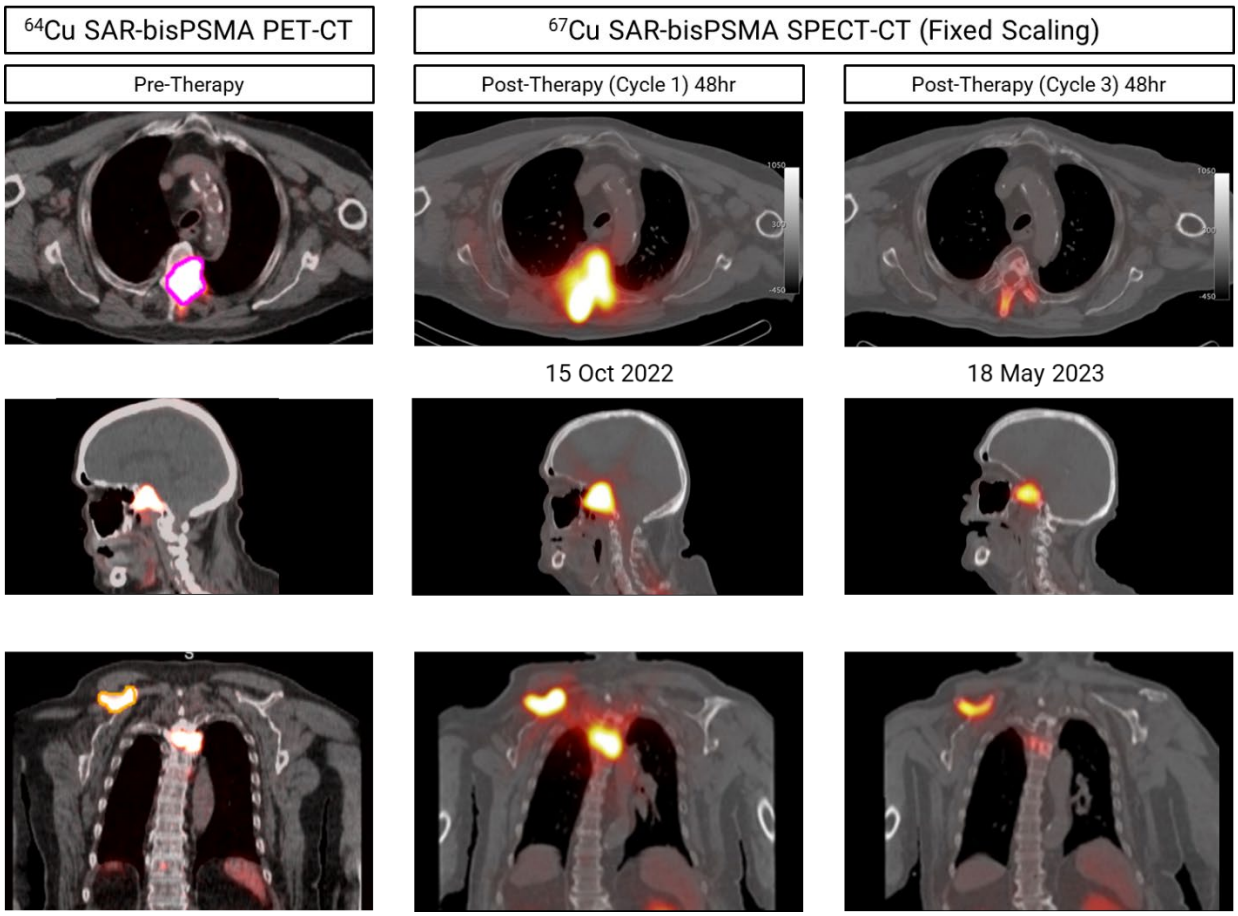
Clarity Pharmaceuticals (ASX: CU6) ("Clarity", "the Company"), a clinical stage radiopharmaceutical company with a mission to develop next-generation products that improve treatment outcomes for children and adults with cancer, is pleased to announce the completion of cohort 1 and advancement to cohort 2 in the therapeutic phase of its Phase I/II theranostic trial, SECuRE, evaluating ^{64}Cu/^{67}Cu SAR-bisPSMA in patients with mCRPC.

The SECuRE trial (NCT04868604)[1] is a Phase I/IIa theranostic trial for identification and treatment of Prostate-Specific Membrane Antigen (PSMA) expressing mCRPC using Targeted Copper Theranostics (TCTs). ^{64}Cu SAR-bisPSMA is used to visualise PSMA expressing lesions and select candidates for subsequent ^{67}Cu SAR-bisPSMA therapy. The trial is a multi-centre, single arm, dose escalation trial with a cohort expansion involving up to 44 patients in the US. The aim of this trial is to determine the safety and efficacy of ^{67}Cu SAR-bisPSMA for the treatment of prostate cancer.

The first cohort of the dose escalation, where 6 participants received a single administration of 4GBq of ^{67}Cu SAR-bisPSMA, has been completed. The SRC, responsible for assessing safety of participants and overseeing the general progress of the trial, has assessed the data and recommended progressing the trial to cohort 2, increasing the dose to 8GBq. No DLTs have been reported in any of the patients dosed to date.

Outside of the trial, therapy cycles of ^{67}Cu SAR-bisPSMA have also been requested by clinicians under the FDA EAP for patients who participated in cohort 1, and data from the EAP continues to be generated.

SPECT-CT images depicted below were collected 48 hours after the first and third administrations of ^{67}Cu SAR-bisPSMA in a patient in the EAP. PET-CT images using ^{64}Cu SAR-bisPSMA were collected prior to therapy. Images collected 48 hours following the third therapy cycle demonstrate a reduction in the intensity of product uptake at the tumour sites. A reduction of greater than 50% in PSA levels was observed in this patient following the first administration of 4GBq of ^{67}Cu-SAR-bisPSMA. PSA decline of 50% or greater is one of the primary endpoints of the SECuRE trial and a commonly used surrogate endpoint for efficacy in this patient population.



Dr Luke Nordquist, CEO, Urologic Medical Oncologist and Principal Investigator at the Urology Cancer Center / XCancer Omaha, NE, commented, "We are excited to have successfully completed the first cohort of the SECuRE trial. We have not seen any safety issues in the patients treated so far and are already seeing clinical benefits in some patients. Outside of reductions in PSA levels and changes in tumour imaging, we have seen an improvement in quality-of-life measures such as reduction in pain and return of appetite and physical exercise. It is fantastic to see benefits at the lowest dose level, and we look forward to progressing to cohort 2 and increasing the dose of ^{67}Cu SAR-bisPSMA."

Clarity's Executive Chairperson, Dr Alan Taylor, commented, "For this product, we went back to the drawing board. We saw the limitations of first-generation PSMA agents, with single PSMA targeting molecules, including low uptake in tumours and poor retention over time. Utilising two PSMA targeting molecules in our optimised agent, bisPSMA, and the TCT platform, we have observed two to three times the uptake of product in tumours so far in pre-clinical and clinical development and saw retention in the tumours out to 96 hours. We are excited by the results of this innovation seen to date as we work towards developing best-in-class products across both diagnostic and therapeutic applications.

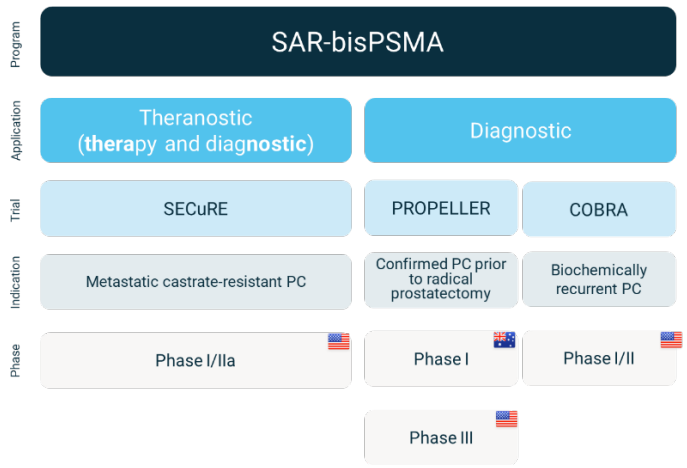
"Prostate cancer is one of the largest oncology indications worldwide and based on our estimates, represents a US$5-10 billion therapy market. Radiopharmaceuticals are expected to play an increasingly important role in the management of patients with prostate cancer, however, challenges associated with the current generation of products prevail. The most recent example is a supply disruption associated with the roll-out of Novartis' US FDA-approved Pluvicto™ (lutetium Lu 177 vipivotide tetraxetan). Despite the significant demand from patients and the product's strong initial sales, with US$211 million in revenue achieved in the first quarter of 2023, Novartis is unable to meet the demand. Manufacturing challenges have crippled the rollout and added to the suffering of patients and their families. Furthermore, reliance on a small number of ageing nuclear reactors to produce lutetium-177 also jeopardises expansion into other cancer indications and undermines the confidence of clinicians and their patients in radiopharmaceuticals.

"Clarity's TCT platform represents the next-generation platform in radiopharmaceuticals to improve treatment outcomes for children and adults with cancer as well as resolve the supply and manufacturing issues associated with the first generation of products. Because of these characteristics, TCTs are ideally positioned to enable the field to expand into the oncology market, addressing large indications such as prostate cancer and beyond. Our therapeutic products are based on copper-67, a radioisotope produced on electron accelerators, which are relatively inexpensive and infinitely more scalable in comparison to nuclear reactors. TCTs also do not require heating during the

manufacturing process, minimising quality concerns and making it less costly to manufacture. Production of TCTs has favourable environmental characteristics in comparison to the current generation of theranostics, with a smaller logistical footprint and minimal radioactive waste disposal issues. In a field with too many unforeseen product outages, TCTs enable a reliable and sustainable supply of radiopharmaceuticals.

"Given the myriad of logistical and manufacturing advantages of TCTs, we are committed to completing our clinical trials and bringing this next generation of radiopharmaceuticals to patients around the world."

Overview of Clarity's SAR-bisPSMA clinical trial program



About SAR-bisPSMA

SAR-bisPSMA derives its name from the word "bis", which reflects a novel approach of connecting two PSMA binding motifs to Clarity's proprietary sarcophagene (SAR) technology that securely holds copper isotopes inside a cage-like structure, called a chelator. Unlike other commercially available chelators, the SAR technology prevents copper leakage into the body. SAR-bisPSMA is a TCT that can be used with isotopes of copper-64 (Cu-64 or ^{64}Cu) for imaging and copper-67 (Cu-67 or ^{67}Cu) for therapy.

^{64}Cu SAR-bisPSMA and ^{67}Cu SAR-bisPSMA are unregistered products. Individual results may not represent the overall safety and efficacy of the products. The data outlined in this announcement has not been assessed by health authorities such as the FDA. A clinical development program is currently underway to assess the efficacy and safety of these products. There is no guarantee that these products will become commercially available.

About Prostate Cancer

Prostate cancer is the second most common cancer diagnosed in men globally and the fifth leading cause of cancer death worldwide[2]. The American Cancer Institute estimates in 2023 there will be 288,300 new cases of prostate cancer in the US and around 34,700 deaths from the disease[3].

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 TCTs based on its SAR technology platform for the treatment of children and adults with cancer.

www.claritypharmaceuticals.com

References

1. ClinicalTrials.gov Identifier: NCT04868604, https://clinicaltrials.gov/ct2/show/NCT04868604
2. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries, https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.21660
3. American Cancer Society: Key Statistics for Prostate Cancer, https://www.cancer.org/cancer/prostate-cancer/about/key-statistics.html

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