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First patient treated in Clarity's therapeutic prostate cancer trial

Highlights

- **Clarity Pharmaceuticals recruits and treats its first patient in the therapeutic phase of its SAR-bisPSMA theranostic clinical trial SECuRE (NCT04868604)[1] investigating Targeted Copper Theranostics (TCTs) in patients with metastatic castrate-resistant prostate cancer (mCRPC)**
- **Data from the initial dosimetry phase with ^{64}Cu SAR-bisPSMA was assessed by the Safety Review Committee which recommended to move to therapeutic applications with ^{67}Cu SAR-bisPSMA**
- **The promising preclinical and clinical results to date support Clarity's investigation of the optimised SAR-bisPSMA product in additional oncology indications where the theranostic approach may have utility**

Clarity Pharmaceuticals (ASX: CU6) ("Clarity"), 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 dosing of the first patient in the therapeutic phase of its Phase I/II theranostic trial evaluating ^{64}Cu/^{67}Cu SAR-bisPSMA theranostic products in patients with metastatic, castrate-resistant prostate cancer (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 study with a cohort expansion planned for up to 44 patients in the US. The aim of this trial is to determine the safety and efficacy of ^{67}Cu-SAR-bisPSMA as a therapy.

The SECuRE trial initially underwent the dosimetry phase with ^{64}Cu SAR-bisPSMA to determine product biodistribution and dosimetry over multiple time points. Upon the completion of the phase, the data was collected and reviewed by the Safety Review Committee, which has recommended the trial progresses into therapeutic applications with ^{67}Cu SAR-bisPSMA. The first patient in the therapeutic phase was treated at the Urology Cancer Center and GU Research Network in Omaha, Nebraska.

Dr Luke Nordquist, CEO, Urologic Medical Oncologist and Principal Investigator at the Urology Cancer Center and GU Research Network in Omaha, Nebraska, commented, "We are excited to have successfully treated the first participant with the therapeutic ^{67}Cu SAR-bisPSMA product. The preclinical and preliminary clinical data to date indicates potential diagnostic and therapeutic benefits of the optimised PSMA agent and we look forward to generating further evidence as we progress the recruitment into the SECuRE trial.

"GURN is now recruiting participants in three clinical trials with Clarity's TCTs. We firmly believe that this next-generation platform will help to overcome the logistical and manufacturing challenges that currently plague the radiopharmaceutical field. With an on-demand distribution model that alleviates the reliance on antiquated nuclear reactors, TCTs hold great promise of shifting the treatment paradigm towards the patients and their treatment staff. This way, the clinicians can focus on providing the best patient care without the fear of reactor shutdowns or manufacturing outages disrupting the treatment process."

Clarity's Executive Chairman, Dr Alan Taylor, commented, "Clarity is excited to progress our second theranostic trial and continue exploring the benefits of TCTs. Prostate cancer is one of the largest oncology indications and there is a significant unmet need for improved diagnosis and therapy of patients with this insidious disease. Moreover, the preliminary data suggests the optimised PSMA product could deliver clinical benefits in oncology indications beyond prostate cancer, which we are excited to explore in the near future.

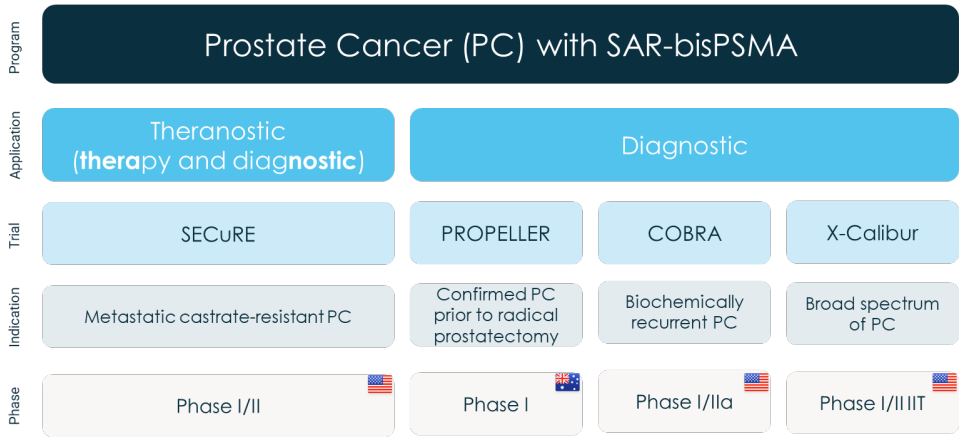
"Radiopharmaceuticals have a great opportunity of advancing the treatment paradigm for cancer patients, however, a number of challenges associated with the current generation products prevail. Firstly, production of currently approved

therapeutic radiopharmaceuticals relies on an ageing fleet of nuclear reactors where shutdowns and interruptions are common. In addition, most currently approved therapeutic products need to be heated during the manufacturing process, which can cause potential quality issues. Finally, as the radiopharmaceutical field is expanding in the global oncology market, the environmental considerations, associated with inefficient supply chains and production of radioactive waste, become a concern.

"Clarity's TCTs are the next-generation platform that aims to resolve these challenges and enable the radiopharmaceutical field to expand significantly in the large oncology market, addressing multiple large cancer indications. Our therapeutic products are based on copper-67 radioisotopes produced on electron accelerators, which are relatively inexpensive and infinitely scalable in comparison to medical nuclear reactors. TCTs also do not require heating during the manufacturing process, making it less costly and minimising quality concerns. Production of TCTs has favourable environmental characteristics in comparison to the current generation of theranostics with smaller infrastructure footprint and minimal radioactive waste disposal issues. In a field with too many unforeseen product outages and manufacturing issues, TCTs enable reliable and sustainable supply of radiopharmaceuticals.

"Given the myriad of logistical and manufacturing advantages of TCTs, we are committed to further validating the promising preclinical and clinical data to date and driving SAR-bisPSMA development in prostate cancer as well as other oncology indications with high unmet need," **said Dr Taylor.**

Clarity's SAR-bisPSMA clinical trial program overview



About SAR-bisPSMA

SAR-bisPSMA derives its name from the word "bis", which reflects a novel approach of connecting two prostate-specific membrane antigen (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 Targeted Copper Theranostic (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.

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 National Cancer Institute estimates in 2022 there will be 268,490 new cases of prostate cancer in the US and around 34,500 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 targeted copper theranostics based on its SAR Technology Platform for the treatment of cancer in children and adults.

www.claritypharmaceuticals.com

References

1. ClinicalTrials.gov Identifier: NCT04839367 <https://clinicaltrials.gov/ct2/show/NCT04839367>
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, Cancer Statistics Center, <https://cancerstatisticscenter.cancer.org/?_ga=2.79808020.284532473.1620009137-1916069442.1615761164#!/cancer-site/Prostate>

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