ASX MEDIA RELEASE

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First patient treated in Clarity's Cu-64/Cu-67 SAR-bisPSMA theranostic prostate cancer trial

Clarity Pharmaceuticals (ASX: CU6) ("Clarity" or the "Company"), an Australian-based clinical stage radiopharmaceutical company developing next-generation products to address the growing need in oncology, is pleased to announce that the first US patient has been dosed with ^{64}Cu SAR-bisPSMA in the dosimetry phase of the SECuRE clinical trial (NCT04868604)[1] investigating Targeted Copper Theranostics (TCTs) in patients with metastatic castrate resistant prostate cancer (mCRPC) at the Urology Cancer Center and GU Research Network in Omaha, Nebraska.

Clarity's Executive Chairman, Dr Alan Taylor, commented, "We are very excited to have treated our first US patient in the SECuRE trial for mCRPC using our optimised PSMA agent, $^{64/67}$Cu SAR-bisPSMA, and look forward to recruiting additional patients and opening all seven clinical sites selected for this trial in the US. We believe the central manufacture, logistical and treatment advantages of TCTs using copper-64 and copper-67 in large patient populations such as prostate cancer will benefit both clinicians and patients.

The SECuRE trial is a Phase I/IIa theranostic trial for identification and treatment of PSMA-expressing mCRPC using TCT. ^{64}Cu SAR-bisPSMA is used to image and select patients for ^{67}Cu SAR-bisPSMA therapy. The initial dosimetry phase utilises ^{64}Cu SAR-bisPSMA to determine biodistribution and dosimetry over multiple time points. The entire 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.

Dr Luke Nordquist, CEO, Urologic Medical Oncologist at the Urology Cancer Center and GU Research Network in Omaha, Nebraska, who treated the first patient with ^{64}Cu SAR-bisPSMA in the trial, commented on this milestone, "$^{64/67}$Cu SAR-bisPSMA products hold great promise of improving prostate cancer diagnosis and treatment and have the potential to provide significant supply benefits in comparison to current products in the market. We look forward to working together with Clarity to explore these benefits and utilise them to improve the lives of men with this insidious disease."

Dr Taylor said: "The prostate cancer market is a key focus for Clarity. The news of the SECuRE trial recruitment milestone comes shortly after treating our first patient in the PROPELLER trial, a diagnostic ^{64}Cu SAR-bisPSMA clinical trial in patients with confirmed prostate cancer (NCT04839367)[2]. We are excited to now have two clinical trials in prostate cancer actively recruiting and treating patients and to build on the compelling results from our therapeutic and diagnostic preclinical studies. We look forward to progressing these trials and getting closer to achieving our ultimate goal of developing better treatments for children and adults with cancer."

Clarity's proprietary SAR Technology platform can be used to develop a range of theranostic radiopharmaceuticals that target different types of cancer. At the heart of Clarity's theranostic SAR Technology platform is a highly specific and highly stable bifunctional chelator (cage) that strongly binds and retains copper isotopes within it. The cage is linked to a targeting molecule, which finds and binds tumour specific receptors on cancer cells. Together with the targeting molecule and the isotope, the technology enables the development of radiopharmaceuticals for diagnosis and therapy in oncology.

About Prostate Cancer

Prostate cancer is the second most common cancer diagnosed in men globally and the fifth leading cause of cancer death worldwide[3]. In 2021, the National Cancer Institute estimated 248,530 new cases of prostate cancer in the US and around 34,130 deaths from the disease[4]. Annually, there are around ~34,000 men in the US who are diagnosed with mCRCP[5], ~90% of whom have tumours which express PSMA[6].

References

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3. 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

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5. 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 Board.

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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/