

ASX MEDIA RELEASE

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## Recruitment complete for Clarity's PROPELLER prostate cancer diagnostic trial

**Clarity Pharmaceuticals** (ASX: CU6) ("Clarity"), a clinical-stage radiopharmaceutical company developing next-generation products to address the growing needs in oncology, is pleased to announce the completion of recruitment for the Phase I PROPELLER diagnostic trial evaluating its  $^{64}\text{Cu}$ -SAR-bisPSMA product candidate in patients with untreated, confirmed prostate cancer, scheduled for radical prostatectomy. A total of 30 participants have been enrolled in the trial<sup>1</sup> across multiple clinical sites in Australia under the supervision of Lead Principal Investigator, Prof Louise Emmett, at St Vincent's Hospital in Sydney.

Clarity expects to report topline results data from the PROPELLER trial in the coming months following the completion of study assessments for all participants and once data analysis activities are finalised. The data will inform a planned registrational Phase III trial in participants with untreated, confirmed prostate cancer in the US.

**Prof Louise Emmett commented**, "The initial imaging data from the PROPELLER trial with the SAR-bisPSMA product looks very encouraging and we look forward to supporting the comprehensive analysis in due course. Having recently also seen the benefits of Clarity's SAR-Bombesin product in breast and prostate cancer patients, there is now growing interest from oncology professionals in Targeted Copper Theranostics (TCTs), particularly due to the efficacy and added flexibility that Clarity's copper-based products provide for patients. Coupled with the logistical benefits TCTs offer through on-demand distribution of ready-to-use products, these may be significant advantages in comparison to the current generation of radiopharmaceuticals. These benefits mean that critical imaging scans can be delivered to cancer patients on time and at a convenient location, representing a treatment paradigm focused on the needs of patients and their treating staff."

**Clarity's Executive Chairman, Dr Alan Taylor, commented**, "We are very pleased to have reached full recruitment in our PROPELLER trial. In this trial we are comparing the diagnostic efficacy of  $^{64}\text{Cu}$  SAR-bisPSMA to the prostate cancer tissue samples (i.e. histology), as well as seeing how the images compare to  $^{68}\text{Ga}$ -PSMA-11, a product that is currently approved in Australia and the United States. We are looking forward to seeing whether the image comparisons in the clinic follow our preclinical observations of higher uptake into tumours with our SAR-bisPSMA product. This is critical in providing a correct diagnosis, especially in patients with early disease. The data from the PROPELLER trial will then inform us on our Phase III trial protocol and commencement of this next trial in calendar year 2023. We look forward to further progressing our SAR-bisPSMA product to improve treatment outcomes for cancer patients."

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

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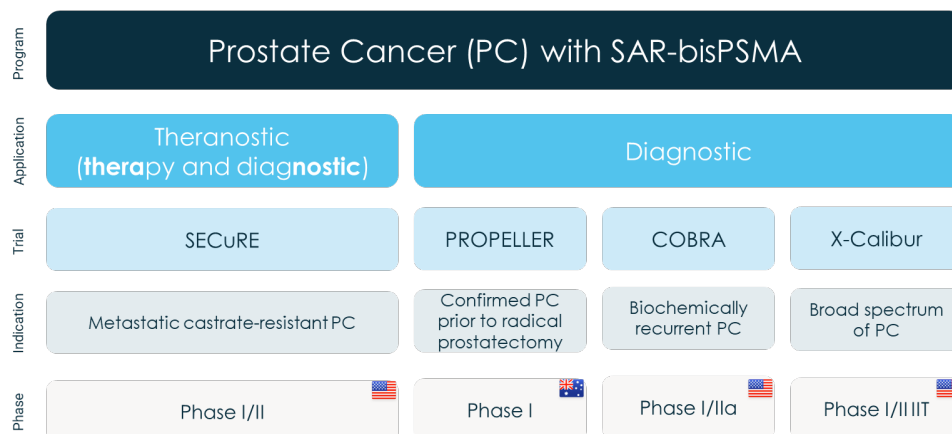
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#### About the PROPELLER Phase I trial

The PROPELLER trial is a Phase I Positron Emission Tomography (PET) imaging trial of participants with confirmed prostate cancer using Clarity's optimised PSMA agent,  $^{64}\text{Cu}$  SAR-bisPSMA. It is a 30-patient multi-centre, blinded review, dose ranging, non-randomised study of  $^{64}\text{Cu}$ -SAR-bisPSMA administered to patients with confirmed prostate cancer prior to radical prostatectomy ([NCT04839367](https://clinicaltrials.gov/ct2/show/study/NCT04839367))<sup>1</sup>. The trial will evaluate the safety, tolerability and efficacy of  $^{64}\text{Cu}$  SAR-bisPSMA in detecting prostate cancer at three dose levels. It will also compare the diagnostic properties of  $^{64}\text{Cu}$  SAR-bisPSMA against  $^{68}\text{Ga}$  PSMA-11, the standard of care for prostate cancer imaging in Australia.

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 <sup>64</sup>Cu) for imaging and copper-67 (Cu-67 or <sup>67</sup>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<sup>2</sup>. 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<sup>3</sup>.

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](http://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](https://cancerstatisticscenter.cancer.org/?_ga=2.79808020.284532473.1620009137-1916069442.1615761164#!/cancer-site/Prostate)