ASX ANNOUNCEMENT

17 July 2025

Co-PSMA trial: Recruitment successfully completed

Clarity Pharmaceuticals (ASX: CU6) ("Clarity" or "Company"), a clinical-stage radiopharmaceutical company with a mission to develop next-generation products that improve treatment outcomes for patients with cancer, is pleased to announce that the Co-PSMA (NCT06907641)[1] Investigator-Initiated Trial (IIT) led by Prof Louise Emmett at St Vincent's Hospital Sydney has now completed study enrolment, with all participants having been imaged.

The study is evaluating the performance of Clarity's diagnostic product, ^{64}Cu-SAR-bisPSMA, in comparison to standard-of-care (SOC) ^{68}Ga-PSMA-11 for the detection of prostate cancer recurrence in patients with low prostate-specific antigen (PSA) who are candidates for curative salvage therapy.

Co-PSMA (Comparative performance of ^{64}Coepper [^{64}Cu]-SAR-bisPSMA vs. ^{68}Ga-PSMA-11 PET CT for the detection of prostate cancer recurrence in the setting of biochemical failure following radical prostatectomy) is a prospective, Phase II imaging trial in 50 patients in biochemical recurrence (BCR) of prostate cancer. Eligible patients were required to have had radical prostatectomy with no salvage therapy and a PSA between 0.2 and 0.75 ng/mL. The primary objective of the trial is to compare the detection rate of sites of prostate cancer recurrence, as determined by number of lesions per patient, between ^{64}Cu-SAR-bisPSMA and ^{68}Ga-PSMA-11 PET/CT.

The diagnostic capabilities of ^{64}Cu-SAR-bisPSMA compared to SOC diagnostic imaging have been demonstrated in two prospective clinical trials, PROPELLER[2] and COBRA[3]. Following the positive results of these trials, Clarity is conducting two Phase III registrational trials, CLARIFY[4] and AMPLIFY[5], in the pre-prostatectomy and BCR settings, respectively. The CLARIFY trial is recruiting patients at St Vincent's Hospital Sydney and this site will also open recruitment for the AMPLIFY trial shortly with Prof Emmett as the principal investigator.

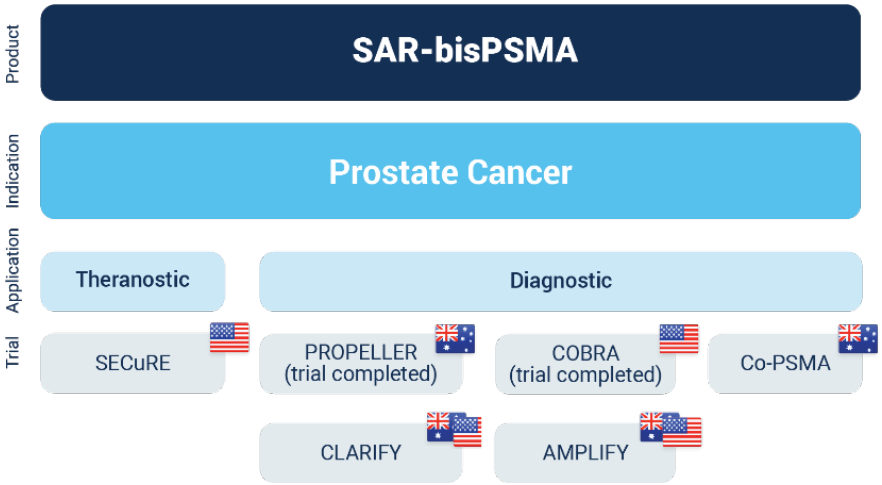
Dr Alan Taylor, Executive Chairperson of Clarity Pharmaceuticals, commented: "We are excited about this important milestone in the Co-PSMA trial and the development program of ^{64}Cu-SAR-bisPSMA. With mounting data of the benefits that ^{64}Cu-SAR-bisPSMA could offer compared to SOC diagnostic imaging, demonstrated in the PROPELLER and COBRA trials, we eagerly anticipate the results from this head-to-head trial against ^{68}Ga-PSMA-11.

"The high volume of patients imaged in recent months at a single site reflects the high unmet need for more effective diagnostic tools for men with rising PSA following radical prostatectomy. Visualising cancer early in these patients is crucial for physicians to determine the optimal course of treatment before the cancer spreads, leading to improved outcomes, including the potential for cure. We are very pleased to be able to support Prof Emmett, a world-renowned thought leader in the theranostics space, through the Co-PSMA trial in our own city of Sydney. We are honoured to continue working together on our pipeline of Targeted Copper Theranostics (TCTs) at St Vincents Hospital Sydney, as it is already actively recruiting patients for the CLARIFY trial and preparing to open enrolment for the AMPLIFY trial shortly."

Prof Louise Emmett (St Vincent's Hospital Sydney), Principal Investigator in the Co-PSMA trial, commented, "We are pleased to have reached our enrolment target for the Co-PSMA trial. Imaging prostate cancer patients has evolved significantly in recent years, particularly with the development of the current-generation PSMA targeted products. The approved PSMA PET products have high specificity, however, due to their low sensitivity, especially in patients with low PSA, a considerable proportion of patients have no detectable disease on the scans while their PSA continues to rise, indicating recurrence of their cancer. With no clear visualisation of where the cancer is located, planning effective treatments is challenging. Early intervention is essential in order to achieve cure in BCR, and the need for more sensitive diagnostics remains. This unmet need is what led us to design the Co-PSMA study.

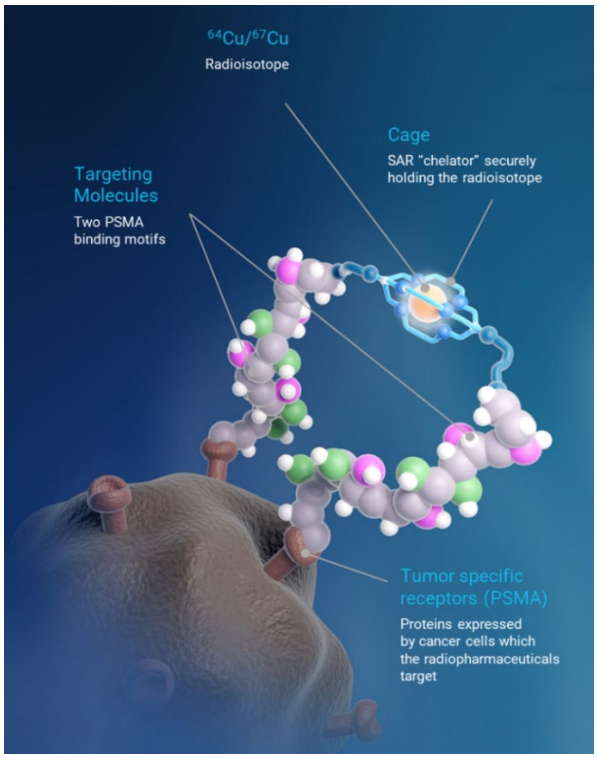
"The data generated thus far on ^{64}Cu-SAR-bisPSMA in the PROPELLER and COBRA trials are very encouraging. The high lesion uptake and retention of the product over time provides better visualisation on same-day imaging compared to SOC imaging. Furthermore, the delayed imaging, enabled by the longer half-life of copper-64 compared to gallium-68 and fluorine-18, increases image contrast, helping to identify smaller lesions and allowing more flexible scheduling of patients. If the Co-PSMA trial confirms that ^{64}Cu-SAR-bisPSMA can detect more lesions than ^{68}Ga-PSMA-11 in this patient group with such low PSA, this may improve image-guided therapy, potentially avoiding complications and improving outcomes. We look forward to reporting the trial results in the coming months."

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-targeting agents to Clarity's proprietary sarcophagine (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.



Disclaimer

^{64}Cu-SAR-bisPSMA is an unregistered product. The safety and efficacy of ^{64}Cu-SAR-bisPSMA has not been assessed by health authorities such as the US Food and Drug Administration (FDA) or the Therapeutic Goods Administration (TGA). There is no guarantee that this product 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 in men worldwide[6]. Prostate cancer is the second-leading causes of cancer death in American men. The American Cancer Institute estimates in 2025 there will be about 313,780 new cases of prostate cancer in the US and around 35,770 deaths from the disease[7].

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References

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7. American Cancer Society: Key Statistics for Prostate Cancer, https://www.cancer.org/cancer/prostate-cancer/about/key-statistics.html

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