ASX ANNOUNCEMENT

14 October 2025

Co-PSMA trial achieves primary endpoint

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 achieved its primary endpoint with a statistically significant higher number of prostate-specific membrane antigen (PSMA)-positive prostate cancer lesions detected using ^{64}Cu-SAR-bisPSMA compared to standard-of-care (SOC) ^{68}Ga-PSMA-11 positron emission tomography/computed tomography (PET/CT) in patients with low prostate-specific antigen (PSA) levels.

Co-PSMA's official study title is "Comparative performance of ^{64}Copper [^{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". This Phase II IIT is evaluating the performance of Clarity's diagnostic product, ^{64}Cu-SAR-bisPSMA, in comparison to SOC ^{68}Ga-PSMA-11 in 50 patients with low PSA who are candidates for curative salvage therapy. Eligible patients were required to have had radical prostatectomy with no salvage therapy and a PSA level between 0.2 and 0.75 ng/mL.

The Co-PSMA trial has successfully met its primary endpoint, demonstrating that ^{64}Cu-SAR-bisPSMA PET/CT detects significantly more lesions per patient than the SOC, ^{68}Ga-PSMA-11 PET/CT. This result supports the hypothesis that ^{64}Cu-SAR-bisPSMA can improve early detection of recurrence and staging of prostate cancer in patients with low PSA who are candidates for curative salvage therapy. Full analysis of all data generated in the Co-PSMA trial is underway, and results of this study will be presented at an upcoming international conference.

The Co-PSMA topline results corroborate findings from the COBRA trial[2], which investigated the diagnostic performance of ^{64}Cu-SAR-bisPSMA in patients with biochemical recurrence (BCR) of prostate cancer who had a negative or equivocal SOC scan at study entry. In the COBRA study, a subset of participants underwent follow-up SOC PSMA PET imaging. Only 60% of these participants had a positive SOC PSMA PET, while 70% of participants had a positive ^{64}Cu-SAR-bisPSMA PET on same-day imaging and 90% on next-day imaging. The number of lesions across all participants (average sum of lesions across all readers) identified by ^{64}Cu-SAR-bisPSMA was also higher (26.3 lesions on same-day imaging, 52.6 on next-day imaging) than that detected by SOC PET agents (20 lesions). The COBRA trial results showed that ^{64}Cu-SAR-bisPSMA was able to identify lesions more than 6 months earlier than SOC PSMA PET agents, with 6 months being the last follow-up visit for that trial.

The Co-PSMA trial further builds on the growing body of evidence of the enhanced diagnostic performance of ^{64}Cu-SAR-bisPSMA compared to SOC PSMA PET agents, which are known to have low sensitivity, especially in patients with low PSA levels[3,4]. Improvements in sensitivity, as with all diagnostic agents, play a pivotal role in guiding more informed treatment decisions, enabling earlier and more accurate detection of prostate cancer recurrence and ultimately improving patient outcomes.

Dr Alan Taylor, Executive Chairperson of Clarity Pharmaceuticals, commented: "Achieving the primary endpoint in the Co-PSMA trial, which was a head-to-head trial against a SOC competing product, is yet another important step in the development of ^{64}Cu-SAR-bisPSMA as we look to further validate this agent as best-in-class through two registrational trials with two Fast Track Designations (FTDs) under our belt for diagnostic applications and a strong focus on commercialisation.

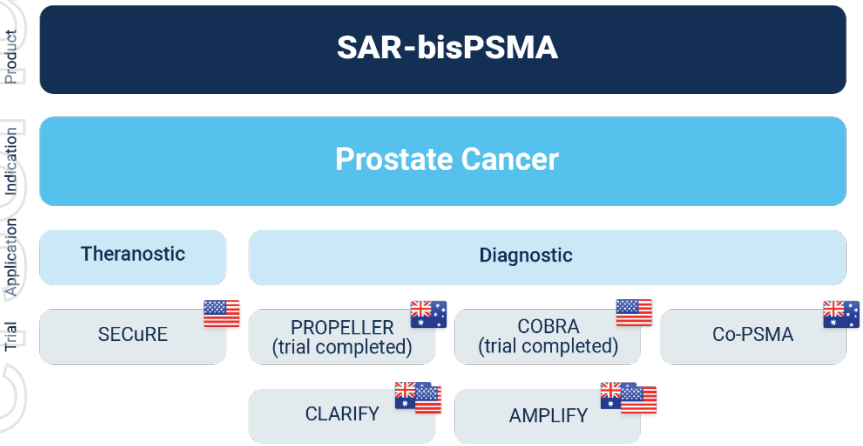
"We look forward to Prof Emmett releasing the full Co-PSMA trial data at world-leading congresses as we continue to adhere to the highest standards of clinical research in our aspirations to bring a best-in-class diagnostic option to men with prostate cancer with clear evidence of superiority. We have already seen in the first-in-human PROPELLER trial an improved diagnostic performance of ^{64}Cu-SAR-bisPSMA compared to ^{68}Ga-PSMA-11 on same-day imaging, including a higher number of lesions identified and 2-3 times higher tumour uptake and tumour-to-background ratio[5]. We then showed in the COBRA trial that approximately twice the amount of lesions was

identified on ^{64}Cu-SAR-bisPSMA PET on next-day vs. same-day imaging, and vs. SOC PSMA PET[2]. ^{64}Cu-SAR-bisPSMA also allowed for the identification of lesions in the 2-mm range, something that SOC PSMA PET agents often fail to achieve[2, 6-9]. This improvement was driven by a substantially increased tumour-to-background ratio and lesion uptake over time with next-day imaging[2].

"The current market for PSMA PET imaging in the US alone is around US$2 billion per year, and this is expected to further grow to over US$3 billion by 2029. However, this entire market is currently served by products that have low sensitivity, while the development pipeline of new products, excluding ^{64}Cu-SAR-bisPSMA, offers no differentiation from the existing agents, with some new entrants commercialising the unpatented ^{68}Ga-PSMA-11 agent, which has been capitalised on by three separate groups already. We believe that with the clinical and logistical benefits offered by ^{64}Cu-SAR-bisPSMA we could not only become the new SOC in PSMA PET but grow the market opportunity further by diagnosing prostate cancer earlier, while lesions are still very small.

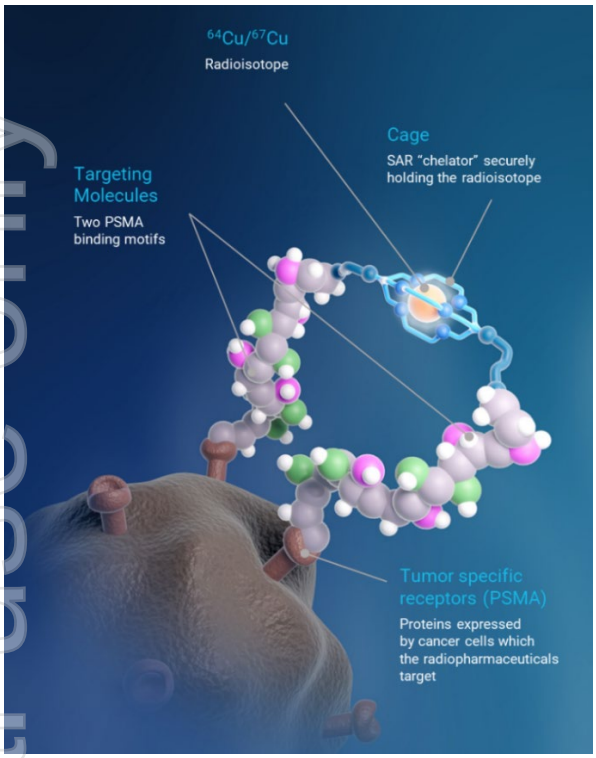
"We look forward to continuing to work with Prof Emmett, a world-renowned thought leader in the radiopharmaceutical space, in our home city of Sydney on progressing clinical development of the ^{64}Cu-SAR-bisPSMA product, including our CLARIFY and AMPLIFY Phase III trials. This partnership will ensure we continue to generate the highest quality of data supporting our New Drug Applications (NDAs) to the US Food and Drug Administration (FDA) as the next step towards our mutual goal of improving treatment outcomes for men with prostate cancer."

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 have not been assessed by health authorities such as the US 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[10]. 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[11].

About Clarity Pharmaceuticals

Clarity is a clinical stage radiopharmaceutical company focused on the treatment of serious diseases. The Company is a leader in innovative radiopharmaceuticals, developing Targeted Copper Theranostics based on its SAR Technology Platform for the treatment of cancers.

www.claritypharmaceuticals.com

For more information, please contact:

Clarity Pharmaceuticals

Dr Alan Taylor
Executive Chairperson
ataylor@claritypharm.com

Lisa Sadetskaya
Director, Corporate Communications
lisa@claritypharm.com

References

1. Clinicaltrials.gov Identifier: NCT06907641, https://clinicaltrials.gov/study/NCT06907641
2. Nordquist et al. COBRA: Assessment of safety and efficacy of ^{64}Cu-SAR-bisPSMA in patients with biochemical recurrence of prostate cancer following definitive therapy. EANM, 2024.
3. Fendler WP et al., Assessment of ^{68}Ga-PSMA-11 PET Accuracy in Localizing Recurrent Prostate Cancer: A Prospective Single-Arm Clinical Trial. JAMA Oncol. 2019 Jun 1;5(6):856-863. doi: 10.1001/jamaoncol.2019.0096. PMID: 30920593; PMCID: PMC6567829.
4. Mena E, Lindenberg ML, Turkbey IB, Shih JH, Harmon SA, Lim I, Lin F, Adler S, Eclarinal P, McKinney YL, Citrin D, Dahut W, Wood BJ, Krishnasamy V, Chang R, Levy E, Merino M, Pinto P, Eary JF, Choyke PL. ^{18}F-DCFPyL PET/CT Imaging in Patients with Biochemically Recurrent Prostate Cancer After Primary Local Therapy. J Nucl Med. 2020 Jun;61(6):881-889. doi: 10.2967/jnumed.119.234799. Epub 2019 Nov 1. PMID: 31676732; PMCID: PMC9374042.
5. Lengyelova & Emmett et al. ^{64}Cu-SAR-bisPSMA (PROPELLER) positron emission tomography (PET) imaging in patients with confirmed prostate cancer. ASCO 2023. Poster available at: https://www.claritypharmaceuticals.com/pipeline/scientific_presentations/
6. Pienta *et al*. A Phase 2/3 Prospective Multicenter Study of the Diagnostic Accuracy of Prostate Specific Membrane Antigen PET/CT with ^{18}F-DCFPyL in Prostate Cancer Patients (OSPREY). Journal of Urology, 2021.
7. Hope et al. Diagnostic Accuracy of ^{68}Ga-PSMA-11 PET for Pelvic Nodal Metastasis Detection Prior to Radical Prostatectomy and Pelvic Lymph Node Dissection. JAMA Oncol, 2021.
8. Petersen *et al*. ^{68}Ga-PSMA PET/CT compared with MRI/CT and diffusion-weighted MRI for primary lymph node staging prior to definitive radiotherapy in prostate cancer: a prospective diagnostic test accuracy study. World Journal of Urology, 2019.
9. Surasi *et al*. Diagnostic Performance and Safety of Positron Emission Tomography with ^{18}F-rhPSMA-7.3 in Patients with Newly Diagnosed Unfavourable Intermediate- to Very-high-risk Prostate Cancer: Results from a Phase 3, Prospective, Multicentre Study (LIGHTHOUSE). European Urology, 2023.
10. 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
11. 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.