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Co-PSMA: Cu-64 SAR-bisPSMA more than doubled prostate cancer lesion and patient detection vs. Ga-68 PSMA-11 in head-to-head trial

HIGHLIGHTS

- Abstract outlining key findings from the Co-PSMA Investigator-Initiated Trial (IIT) has been released.
- The study was led by Prof Louise Emmett at St Vincent's Hospital Sydney, and the abstract was accepted for oral presentation at the upcoming European Association of Urology (EAU) Congress 2026.
- Co-PSMA IIT evaluated the performance of Clarity's diagnostic product, ^{64}Cu-SAR-bisPSMA, in a head-to-head comparison to standard-of-care (SOC) ^{68}Ga-PSMA-11 in 50 patients with biochemical recurrence (BCR) of prostate cancer (with prostate-specific antigen [PSA] 0.2-0.75 ng/mL) following radical prostatectomy who were candidates for curative salvage therapy.
- ^{64}Cu-SAR-bisPSMA positron emission tomography (PET) / computed tomography (CT) identified a statistically significant greater number of prostate cancer lesions per patient than ^{68}Ga-PSMA-11 PET/CT (study primary endpoint). The mean per-patient lesion was 1.26 for ^{64}Cu-SAR-bisPSMA vs. 0.48 for ^{68}Ga-PSMA-11, with a difference of 0.78 (95% confidence interval [CI]: 0.52 – 1.04), ratio 2.63 (95%CI: 1.64 – 4.20) (p <0.0001).
- In total, ^{68}Ga-PSMA-11 identified 24 lesions across all participants, while ^{64}Cu-SAR-bisPSMA next-day imaging detected 63 lesions.
- At a per-patient level, ^{68}Ga-PSMA-11 identified 36% (18/50) of trial participants as having a positive scan, while ^{64}Cu-SAR-bisPSMA next-day imaging detected prostate cancer in 78% (39/50) of cases.
- Planned patient management changed following assessment of ^{64}Cu-SAR-bisPSMA PET/CT in 22/50 (44%) trial participants.
- Further data outlining results from the Co-PSMA IIT will be presented at the EAU Congress 2026.

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 the release of an abstract on the Co-PSMA (NCT06907641)[1] IIT, accepted for oral presentation at the upcoming EAU Congress 2026, Europe's largest urological conference, to be held from 13 to 16 March 2026 in London, UK[2]. The abstract outlines key findings from the study.

Co-PSMA ("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") was led by Prof Louise Emmett at St Vincent's Hospital Sydney. This Phase II IIT evaluated the performance of Clarity's diagnostic product, ^{64}Cu-SAR-bisPSMA, in a head-to-head comparison to SOC ^{68}Ga-PSMA-11 in 50 prostate cancer patients with BCR who were 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. ^{68}Ga-PSMA-11 PET/CT was followed by ^{64}Cu-SAR-bisPSMA PET/CT within 3 weeks (at 1 h and 24 h post-injection, same-day and next-day imaging, respectively), on the same digital PET camera. A standard of truth (SOT) was used to determine accuracy of the PET findings and included biopsy, response to targeted treatment without androgen deprivation therapy [ADT]

or corroborative imaging. The primary endpoint of the Co-PSMA study was to assess the difference in mean per patient lesion number.

^{64}Cu-SAR-bisPSMA PET/CT identified a statistically significant greater number of lesions per participant than ^{68}Ga-PSMA-11 PET/CT, with a higher true positive rate also favouring ^{64}Cu-SAR-bisPSMA. The mean per-patient lesion for ^{64}Cu-SAR-bisPSMA was 1.26, compared to 0.48 for ^{68}Ga-PSMA-11, with a difference of 0.78 (95%CI: 0.52 – 1.04), ratio 2.63 (95%CI: 1.64 – 4.20) (p <0.0001). In total, ^{68}Ga-PSMA-11 identified 24 lesions across all participants, while ^{64}Cu-SAR-bisPSMA next-day imaging detected 63 lesions. On a per patient level, 36% (18/50) of participants were positive on ^{68}Ga-PSMA-11 PET/CT, compared to 78% (39/50) on the ^{64}Cu-SAR-bisPSMA PET/CT (next-day imaging). Planned patient management changed following the assessment of the ^{64}Cu-SAR-bisPSMA scans in 22/50 (44%) trial participants. Among the participants with an evaluable SOT, the true positive rate was 75% for ^{64}Cu-SAR-bisPSMA (21/28) compared to 39% (11/28) for ^{68}Ga-PSMA-11.

These results further build on the growing body of evidence showing that ^{64}Cu-SAR-bisPSMA improves the detection of prostate cancer, compared to the current SOC prostate-specific membrane antigen (PSMA) PET agents which are known to have low sensitivity, with limited ability to detect cancer, especially in patients with low PSA levels[3,4,5].

Further data outlining results from the Co-PSMA IIT will be announced in mid-March following their oral presentation at the EAU 2026.

Clarity's Executive Chairperson, Dr Alan Taylor, commented, "The data from the Co-PSMA trial are nothing short of exceptional. We already knew of the significant benefits of the optimised bisPSMA molecule from the early days around 7 years ago, when it was purposely developed to overcome the many shortfalls of the current single-targeting SOC PSMA imaging agents. This innovative benchtop research of the dual-targeting bisPSMA agent quickly progressed to multiple clinical trials, including COBRA[6], PROPELLER[7] and SECuRE[8], which enabled us to secure three Fast Track Designations from the United States (US) Food and Drug Administration (FDA) and advance to two registrational trials, AMPLIFY[9] and CLARIFY[10], both of which are nearing completion of recruitment.

"Importantly, in the COBRA trial, we also looked at the performance of ^{64}Cu-SAR-bisPSMA in patients with BCR of prostate cancer following definitive therapy, but with participant selection criteria having no limitation on upper PSA levels (median 0.9 ng/mL, range 0.25 to 17.6). The Co-PSMA data we are seeing to date reinforces the COBRA trial findings where more lesions and patients with a positive scan were identified using ^{64}Cu-SAR-bisPSMA compared to SOC PSMA PET products, including ^{68}Ga-PSMA-11 and ^{18}F-DCFPyL[6]. A subset of participants in the COBRA trial had a follow-up SOC PSMA PET. While 90% of these participants had a positive scan on the initial ^{64}Cu-SAR-bisPSMA next-day imaging, only 60% were positive on SOC PSMA PET, despite median scan time from the first ^{64}Cu-SAR-bisPSMA imaging to the follow-up scan being 73.5 days. The number of lesions across all participants (average sum of lesions across all readers) identified by ^{64}Cu-SAR-bisPSMA on next-day imaging was >2.6 times higher than that detected by SOC PET agents (52.6 vs 20 lesions)[6].

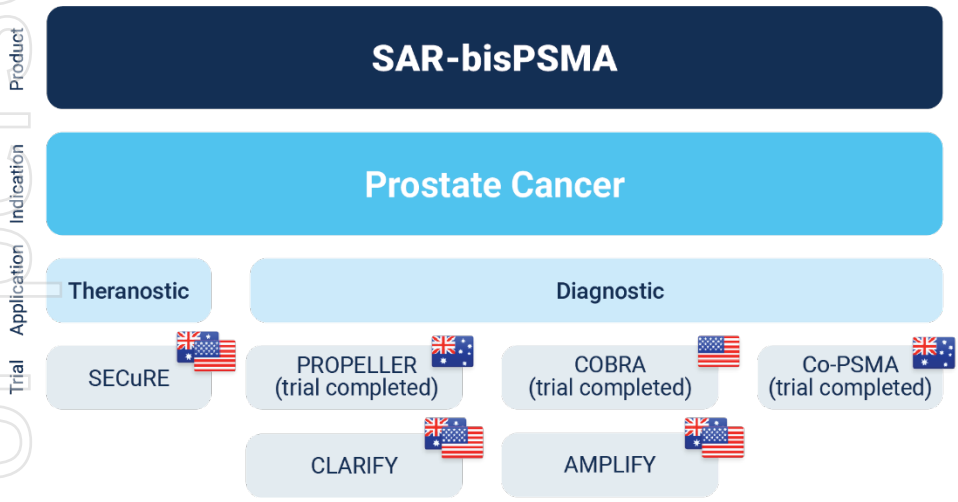
"What we are learning today from the head-to-head Co-PSMA study is a valuable insight into how ^{64}Cu-SAR-bisPSMA directly compares against ^{68}Ga-PSMA-11, further bolstering the data seen to date. Similar to COBRA, Co-PSMA demonstrated that our product was able to identify more than 2.5 times total number of lesions on the next-day imaging in comparison to the SOC. Furthermore, 4 out of every 5 participants had a positive scan for prostate cancer using ^{64}Cu-SAR-bisPSMA, compared to only 2 in 5 participants using ^{68}Ga-PSMA-11, therefore making ^{64}Cu-SAR-bisPSMA far more reliable than ^{68}Ga-PSMA-11 in detecting the presence of cancer in these patients. These findings, coupled with the much higher true positive rate of ^{64}Cu-SAR-bisPSMA (75% vs. 39% for ^{68}Ga-PSMA-11), will enable clinicians to treat prostate cancer more effectively and with a greater level of confidence based on the accurate detection of disease. These results speak for themselves, clearly illustrating that ^{64}Cu-SAR-bisPSMA considerably outperforms its competitors in detecting prostate cancer recurrence. Moreover, this sheds light on the importance of the improved lesion detection, where the diagnostic benefits translate into enhanced patient management: almost half of the Co-PSMA and COBRA study participants had a change of their planned disease management as a result of the ^{64}Cu-SAR-bisPSMA findings[6], which could be absolutely game-changing for clinicians and their patients. This is the difference between allowing prostate cancer lesions to grow or having a clear diagnosis and an active and highly targeted treatment plan. Earlier intervention in BCR can prevent cancer growth and spread, avoid side effects from systemic therapies and considerably improve patient outcomes.

"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. Unfortunately, this blockbuster market is dominated by ^{68}Ga-PSMA-11 and ^{18}F-DCFPyL, both of which have low sensitivity[4,5]. The development pipeline of new products, excluding ^{64}Cu-SAR-bisPSMA, offers no significant 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. Time and time again we are seeing significant clinical and logistical benefits offered by ^{64}Cu-SAR-bisPSMA through our trials. We strongly believe this product could not only become the new SOC in PSMA PET but also grow the market opportunity further by substantially improving the diagnosis of prostate cancer in many stages of the disease, from its early phases pre-definitive therapy, through to better identification of lesions in the BCR setting, including in patients with oligometastatic disease.

"While the AMPLIFY and CLARIFY trials are key to getting ^{64}Cu-SAR-bisPSMA towards commercialisation, Co-PSMA provides further evidence of its benefits to clinicians and prostate cancer patients. This makes the paradigm shift towards improved diagnostics a no-brainer due to our relentless focus on rigorous clinical development and commitment to strong science to change the lives of people living with cancer. The acceptance of the Co-PSMA data by a world-leading urology conference as an oral presentation is a testament to the strength and quality of the data, generated by Prof Emmett, a global key opinion leader in the field."

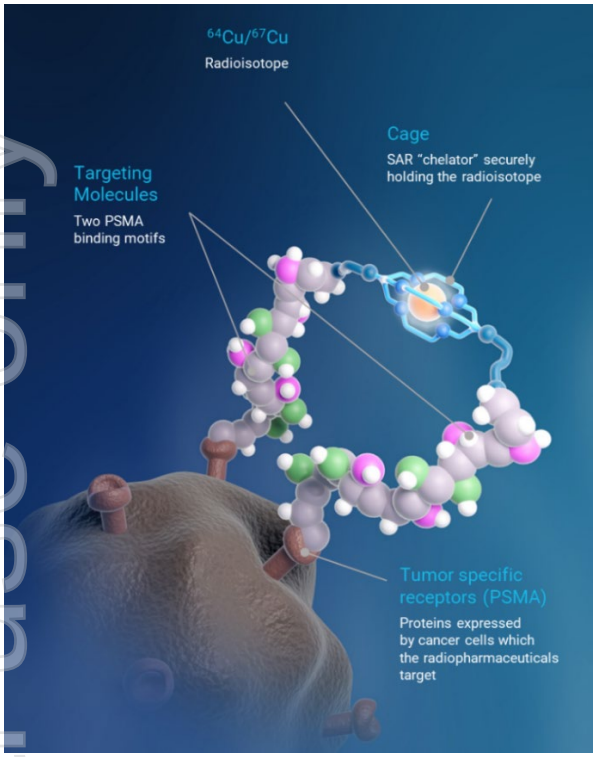
Prof Louise Emmett (St Vincent's Hospital Sydney), Principal Investigator in the Co-PSMA trial, commented, "While approved PSMA PET agents are highly specific, their low sensitivity at low PSA levels means that many patients with early rising PSA show no detectable disease, making treatment planning challenging. More sensitive diagnostics that remain highly specific are needed for effective early intervention in BCR. Our research demonstrates that ^{64}Cu-SAR-bisPSMA PET/CT offers a significant advancement in the detection of recurrent prostate cancer. Compared to ^{68}Ga-PSMA-11, the 24-hour ^{64}Cu-SAR-bisPSMA images identified the site of disease recurrence in a higher proportion of patients, directly informing tailored treatment decisions for men in BCR. These findings highlight the potential for ^{64}Cu-SAR-bisPSMA to improve patient outcomes."

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 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[11]. Prostate cancer is the second-leading causes of cancer death in American men. The American Cancer Institute estimates there will be about 333,830 new cases of prostate cancer in the US in 2026 and around 36,320 deaths from the disease[12].

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.

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References

1. Clinicaltrials.gov Identifier: NCT06907641. https://clinicaltrials.gov/study/NCT06907641
2. EAU26. The Congress. https://eaucongress-new.uroweb.org/the-congress
3. Clarity Pharmaceuticals. Co-PSMA trial achieves primary endpoint. https://www.claritypharmaceuticals.com/news/co-psma-endpoint/.
4. ILLUCIX. Prescribing information. Telix Pharmaceuticals; 2023. www.accessdata.fda.gov/drugsatfda_docs/label/2023/214032s001lbl.pdf
5. PYLARIFY. Prescribing information. Progenics Pharmaceuticals; 2021. www.accessdata.fda.gov/drugsatfda_docs/label/2021/214793s000lbl.pdf
6. Nordquist et al. COBRA: Assessment of ^{64}Cu-SAR-bisPSMA and standard of care prostate-specific membrane antigen Positron Emission Tomography in patients with biochemical recurrence of prostate cancer following definitive therapy. AUA 2025 Annual Meeting.
7. 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/
8. Clinicaltrials.gov Identifier: NCT04868604, https://clinicaltrials.gov/ct2/show/NCT04868604
9. Clinicaltrials.gov Identifier: NCT06970847. https://clinicaltrials.gov/study/NCT06970847
10. Clinicaltrials.gov Identifier: NCT06056830. https://clinicaltrials.gov/study/ NCT06056830
11. 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
12. 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.