ASX ANNOUNCEMENT

17 March 2026

Co-PSMA data presented at EAU Annual Congress 2026 with manuscript accepted for publication in the European Urology journal

HIGHLIGHTS

- Oral presentation on key results from the Co-PSMA (NCT06907641)[1] Investigator-Initiated Trial (IIT) was delivered by Prof Louise Emmett (St Vincent's Hospital Sydney) at the European Association of Urology (EAU) Congress 2026 on the 16th of March 2026 in London, UK[2].
- Co-PSMA trial data has also been accepted for publication in the prestigious European Urology, the official journal of EAU with an impressive impact factor of 25.2.
- Clarity's ^{64}Cu-SAR-bisPSMA (24-hour imaging) demonstrated considerable improvement in diagnostic performance in a head-to-head comparison with standard-of-care (SOC) ^{68}Ga-PSMA-11 positron emission tomography (PET)/computed tomography (CT) in 50 patients with biochemical recurrence (BCR) of prostate cancer with low prostate-specific antigen (PSA; 0.2 – 0.75 ng/mL) who were candidates for curative salvage therapy following radical prostatectomy.
- The study's primary endpoint was to assess the difference in mean per-patient lesion between ^{64}Cu-SAR-bisPSMA and ^{68}Ga-PSMA-11. Key secondary endpoints included evaluation of diagnostic accuracy against composite reference standard and patient management impact.
- Mean per-patient lesion was higher for ^{64}Cu-SAR-bisPSMA (24-hour imaging) vs. ^{68}Ga-PSMA-11 (1.26 vs. 0.48, respectively), difference: 0.78 (95% confidence interval [CI]: 0.52 – 1.04) ratio 2.63 (95% CI: 1.64 – 4.20) ($p < 0.0001$).
- Next-day imaging with ^{64}Cu-SAR-bisPSMA, compared with ^{68}Ga-PSMA-11, identified a greater number of total lesions (63 vs. 24, respectively). The biggest difference in lesion detection between the tracers was in the prostate fossa and in lymph nodes. ^{64}Cu-SAR-bisPSMA also resulted in a higher number of trial participants with a positive scan compared to ^{68}Ga-PSMA-11 (78% vs. 36%, respectively).
- ^{64}Cu-SAR-bisPSMA (24-hour imaging) demonstrated a higher true positive rate (71% vs. 29%) and lower false negative rate (21% vs. 65%) than ^{68}Ga-PSMA-11.
- ^{64}Cu-SAR-bisPSMA next-day imaging resulted in management change in 44% (22/50) of trial participants, with the majority changing from surveillance to targeted radiotherapy.
- Co-PSMA trial data, combined with Phase II COBRA and anticipated results from a pivotal Phase III AMPLIFY study, are intended to be submitted to the United States (US) Food and Drug Administration (FDA) for a market authorisation of ^{64}Cu-SAR-bisPSMA in patients with BCR of prostate cancer.

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 results from the Co-PSMA (NCT06907641)[1] IIT were presented by Prof Louise Emmett (St Vincent's Hospital Sydney) in an oral session at EAU Congress 2026, Europe's largest urological conference, on the 16th March in London, UK[2]. The study data has also been accepted for publication in European Urology, the official journal of EAU with an impressive impact factor of 25.2.

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 a Phase II IIT evaluating 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 patients with low PSA (0.2 – 0.75 ng/mL) who were candidates for curative salvage therapy. Eligible patients were required to have had radical prostatectomy with no salvage therapy. ^{68}Ga-PSMA-11 PET/CT was followed by ^{64}Cu-SAR-bisPSMA PET/CT (at 1 hour and 24 hours post-injection, same-day and next-day imaging, respectively) on the same digital PET camera.[1,3]

The **primary endpoint** of the Co-PSMA study was to assess the difference in mean per patient lesion number. Using a paired means test, a sample size of 50 provided power of 90% to detect a minimum alternative mean difference greater than zero of 0.432. **Secondary endpoints** included management impact questionnaires between ^{64}Cu-SAR-bisPSMA and ^{68}Ga-PSMA-11 and accuracy of the PET findings determined using a comprehensive reference standard, including biopsy, response to targeted treatment without androgen deprivation therapy [ADT], PSA rise without treatment or corroborative imaging.

Overall, ^{64}Cu-SAR-bisPSMA PET/CT (24-hour imaging) was found to identify a higher number of disease recurrences than ^{68}Ga-PSMA-11 PET/CT with substantial management impact and a high true positive rate in men with BCR post-radical prostatectomy.

Participants enrolled had a median PSA of 0.43 (IQR: 0.31 – 0.63) and 74% had an International Society of Urological Pathologists (ISUP) grade of 3 or higher. The mean per-patient lesion for ^{64}Cu-SAR-bisPSMA (24-hour imaging) 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 24-hour ^{64}Cu-SAR-bisPSMA imaging detected 63 lesions (representative image in **Figure 1**). The increase in the number of lesions identified by ^{64}Cu-SAR-bisPSMA was noted in the prostatic bed region (local recurrence), pelvic/extra-pelvic lymph nodes and bone (**Table 1**).

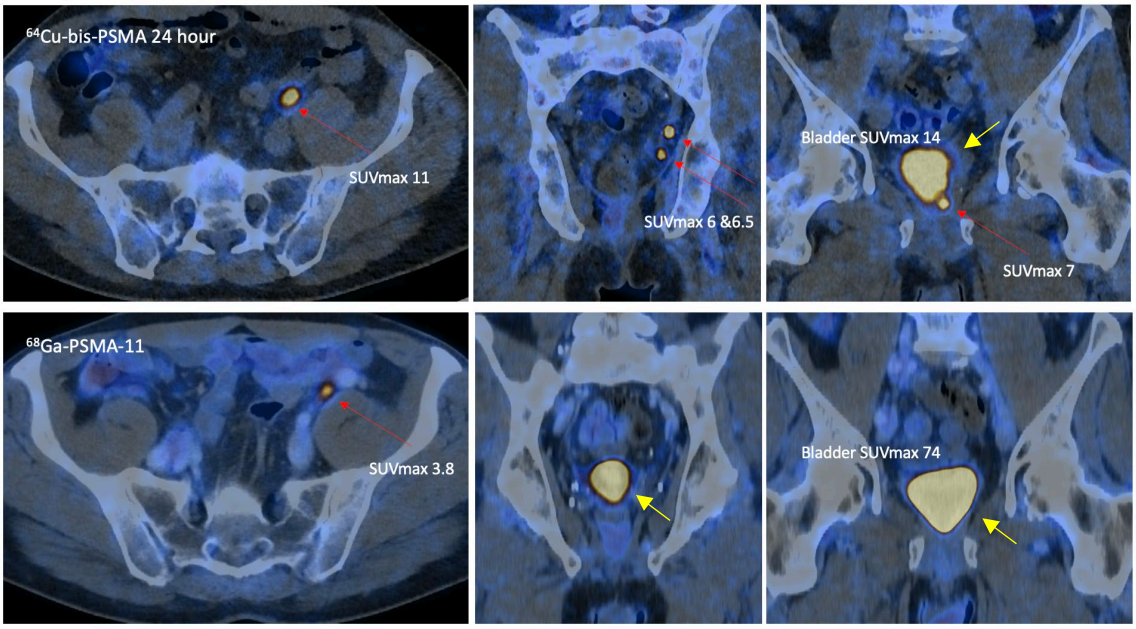


Figure 1. PET/CT of ^{64}Cu-SAR-bisPSMA (top: axial left, coronal centre and right) and ^{68}Ga-PSMA-11 (bottom: axial left, coronal centre and right). The 24-hour ^{64}Cu-SAR-bisPSMA PET/CT identified multiple sites of recurrence (pelvic lymph nodes and fossa), while only a single pelvic lymph node was reported on ^{68}Ga-PSMA-11 PET/CT (red arrows). ^{64}Cu-SAR-bisPSMA demonstrated higher lesion uptake and tumour-to-background contrast, while ^{68}Ga-PSMA-11 showed higher bladder uptake (yellow arrows). Adapted and reproduced with permission from Prof Louise Emmett.

Variable	^{68}Ga-PSMA-11	24-hour ^{64}Cu-SAR-bisPSMA
Number of participants with a positive scan, n/N (%)	18/50 (36%)	39/50 (78%)
Total number of lesions identified (across participants), n	24	63
Location of recurrence, n/N (%)		
Local recurrence	11/50 (22%)	28/50 (56%)
Pelvic or extra-pelvic lymph nodes	4/50 (8%)	10/50 (20%)
Bone	5/50 (10%)	8/50 (16%)
Viscera (lung)	1/50 (2%)	1/50 (2%)

Table 1. Comparison between ^{68}Ga-PSMA-11 and ^{64}Cu-SAR-bisPSMA scans: number of participants with a positive scan and location of recurrence. 24-hour ^{64}Cu-SAR-bisPSMA scans resulted in a higher number of lesions detected and prostate-specific membrane antigen (PSMA) PET-positive participants as compared to ^{68}Ga-PSMA-11 scans. The increase in the number of lesions identified by ^{64}Cu-SAR-bisPSMA was noted in the prostatic bed region (local recurrence), pelvic/extra-pelvic lymph nodes and bone.

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 ^{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 standard of truth (SOT), the true positive rate was 71% for 24-hour ^{64}Cu-SAR-bisPSMA (24/34) compared to 29% (10/34) for ^{68}Ga-PSMA-11. The false negative rate was 21% for 24-hour ^{64}Cu-SAR-bisPSMA (7/34) vs. 65% for ^{68}Ga-PSMA-11 (22/34).

These results from the Co-PSMA IIT further build on the growing body of evidence demonstrating that ^{64}Cu-SAR-bisPSMA improves the detection of prostate cancer compared to the current SOC PSMA PET agents which have lower sensitivity in patients with low PSA levels[4,5]. In the Phase II COBRA trial, ^{64}Cu-SAR-bisPSMA was evaluated in patients with BCR who had a negative or equivocal scan at study entry. Among participants with a follow-up SOC PSMA PET, 90% were positive on 24-hour ^{64}Cu-SAR-bisPSMA PET compared with only 60% on SOC PSMA PET. Overall, next-day imaging with ^{64}Cu-SAR-bisPSMA identified more than 2.6 times lesions than SOC PSMA PET[6]. The COBRA data, combined with the Co-PSMA IIT results, will complement the anticipated findings from the Phase III registrational trial, AMPLIFY, which recently reached its target number of participants[7]. Together, they are intended to be submitted to the US FDA for a market authorisation of ^{64}Cu-SAR-bisPSMA in patients with BCR of prostate cancer.

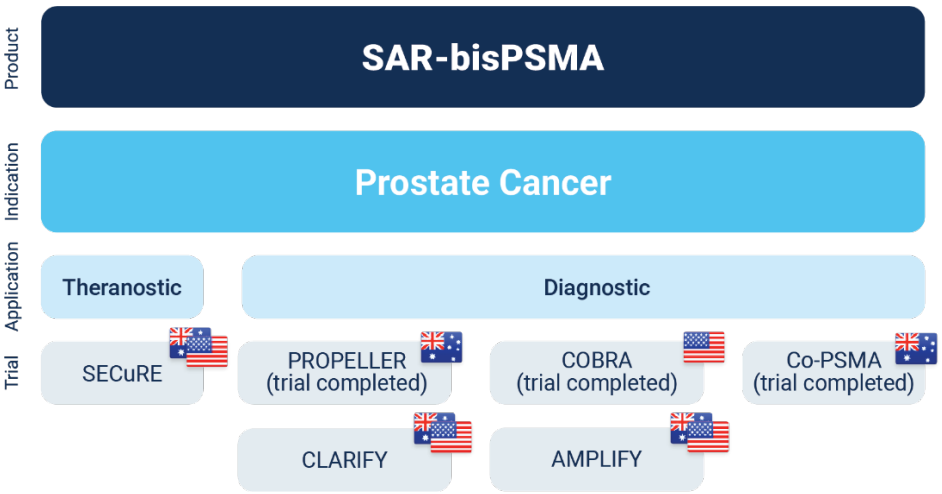
Prof Louise Emmett (St Vincent's Hospital Sydney), Principal Investigator in the Co-PSMA trial, commented, "Head-to-head trials are very important in helping clinicians determine the most appropriate products for their patients. The Co-PSMA study shows that a novel PSMA-targeted PET agent like ^{64}Cu-SAR-bisPSMA can deliver improved imaging performance compared to other SOC PSMA agents. In Co-PSMA, ^{64}Cu-SAR-bisPSMA at 24 hours identified more sites of recurrence and directly informed personalised treatment decisions, highlighting its potential to improve outcomes in prostate cancer patients with BCR."

Clarity's Executive Chairperson, Dr Alan Taylor, commented, "Science underpins the entirety of our biotechnology sector, and as a science-driven organisation, nothing makes us more proud than to see our products progress from the Australian benchtop to now generating excellent results in the clinic and having this substantiated and quantified to the highest standard through the scientific method. We applaud the independent work of Prof Louise Emmett and her team at St Vincent's Hospital in Sydney who chose to progress this trial in such detail, leading to the acceptance of the data in European Urology, a top-tier journal with a high impact factor of 25.2.

"The high quality of these data now adds to the substantial body of evidence supporting our product, the optimised SAR-bisPSMA. The discovery and pre-clinical work has been previously circulated in numerous journals, including publications by our long-term collaborator, Prof Paul Donnelly, sharing his seminal work on the sarcophagine (SAR) chelator as well as on the SARTATE, SAR-Bombesin and the optimised SAR-bisPSMA agents in 2023 in Chemical Reviews[8], one of the highest impact factor journals in chemistry with a 5-year impact factor of 67.5.

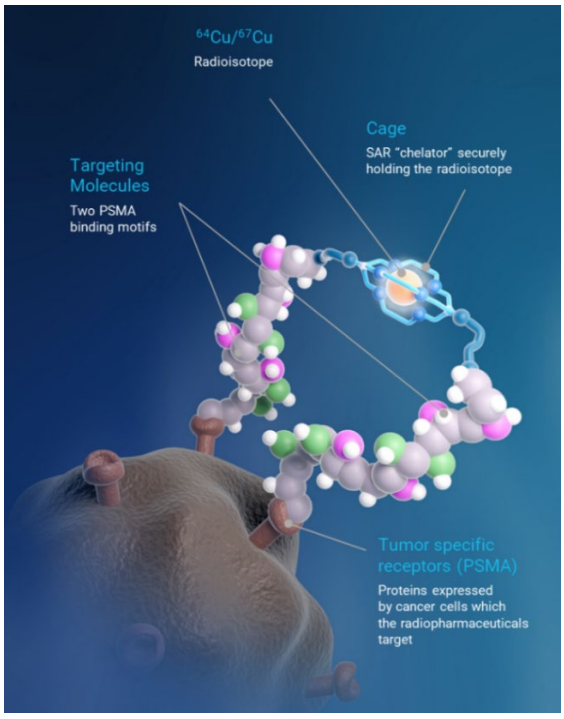
"The extraordinary quality of the academic research is coupled with the feverish pace of commercialisation where our registrational Phase III trials, AMPLIFY and CLARIFY, are nearing completion. We have recently shared that AMPLIFY reached its target number of participants with rising or detectable PSA after initial definitive treatment at clinical sites across the US and Australia in just 9 months since imaging the first patient[7], and we look forward to collecting and analysing the final study data. Combined with results from the Co-PSMA and COBRA trials, we believe it will constitute a compelling application for approval of ^{64}Cu-SAR-bisPSMA by regulatory authorities for the BCR indication. Armed with three Fast Track Designations for the one SAR-bisPSMA agent, we are ready to work closely with the US FDA to get it to patients in need as soon as possible, and we look forward to more positive interactions with the Agency on this journey. As always, we will continue updating the market on the progress of our bisPSMA program, including significant milestones in the AMPLIFY, CLARIFY and SECuRE trials, as well as on the supply chain and regulatory developments as we enter the market with our first product."

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 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 and ^{67}Cu-SAR-bisPSMA are unregistered products. Their safety and efficacy 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[9]. Prostate cancer is the second-leading cause 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[10].

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

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