

## ASX ANNOUNCEMENT

31 March 2026

# Co-PSMA data published in the European Urology journal

**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](#))<sup>1</sup> investigator-initiated trial (IIT) are now published in *European Urology*<sup>2</sup>, the official journal of the European Association of Urology (EAU) Congress 2026 with an impressive impact factor of 25.2.

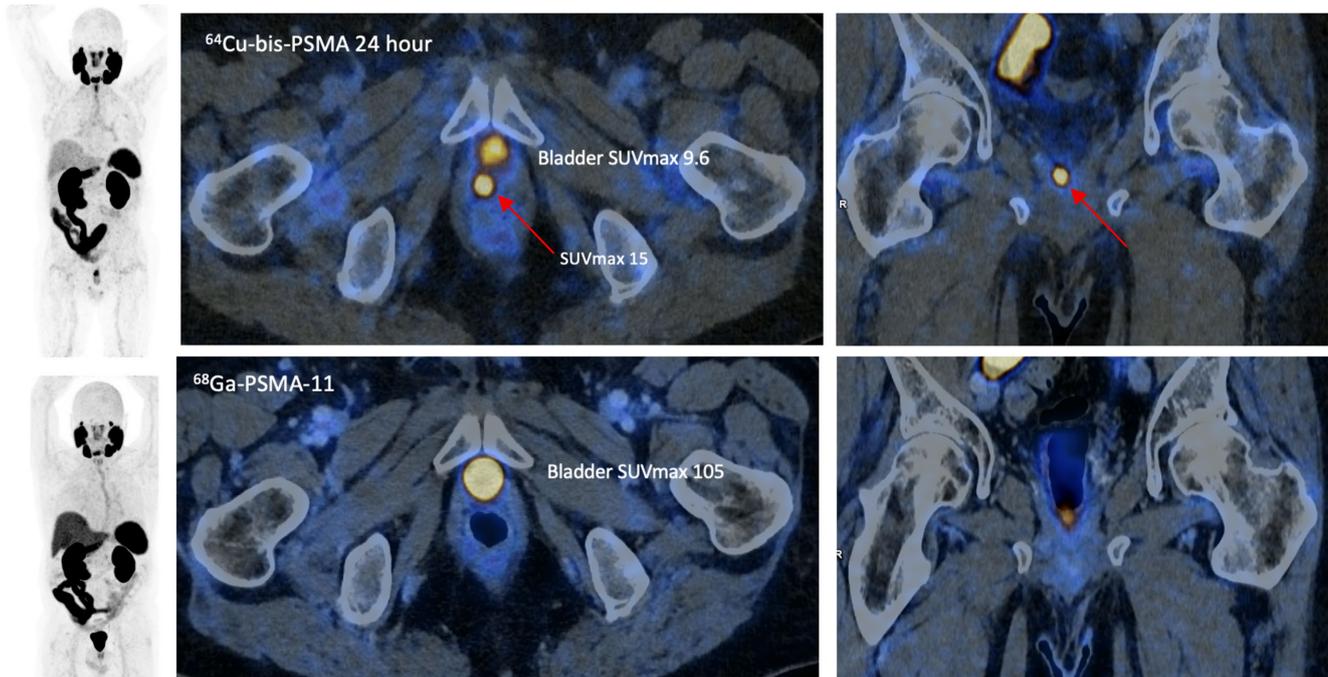
**Gianluca Giannarini (MD), Associate Editor of European Urology, summarised the clinical relevance of the Co-PSMA trial,** “This prospective phase II trial provides the first comparative evidence that 24-hour <sup>64</sup>Cu-SAR-bisPSMA positron emission tomography (PET) / computed tomography (CT) significantly outperforms <sup>68</sup>Ga-PSMA-11 PET/CT in detecting tumour deposits in men with early biochemical recurrence (BCR) after radical prostatectomy, with more than double the per-patient detection rate and substantially lower false-negative findings. Importantly, the increased detection rate translated into a 44% management change rate, underscoring the real-world therapeutic impact of improved lesion detection at low prostate-specific antigen (PSA) levels. For the uro-oncology community, these data suggest that delayed imaging with a bivalent prostate-specific membrane antigen (PSMA) ligand may redefine the diagnostic pathway in early biochemical recurrence, potentially enabling more precise and timely salvage treatment strategies.”

As previously reported, the Co-PSMA trial met its primary endpoint, demonstrating that <sup>64</sup>Cu-SAR-bisPSMA (next-day imaging) identified more than twice as many cancer lesions per patient than <sup>68</sup>Ga-PSMA-11 (mean per patient lesion 1.26 vs. 0.48, respectively,  $p < 0.0001$ ). The total number of lesions across all participants and proportion of participants with a positive scan were also higher with <sup>64</sup>Cu-SAR-bisPSMA (63 vs. 24 total number of lesions and 78% vs. 36% of participants with a positive scan for <sup>64</sup>Cu-SAR-bisPSMA [next-day imaging] vs. <sup>68</sup>Ga-PSMA-11, respectively). The patient-level true positive rate also favoured <sup>64</sup>Cu-SAR-bisPSMA next-day imaging (71% vs. 29% for <sup>68</sup>Ga-PSMA-11)<sup>3</sup>.

Building on the data previously presented at the EAU Congress 2026<sup>3</sup>, the publication provides further methodological and clinical insights supporting the interpretation of the findings. Notably, the median interval between <sup>68</sup>Ga-PSMA-11 and <sup>64</sup>Cu-SAR-bisPSMA imaging was only 2 days (interquartile range [IQR]: 1 – 8 days), ruling out differences in lesion detection due to disease progression. This result is corroborated by previous findings from the COBRA trial, which demonstrated that <sup>64</sup>Cu-SAR-bisPSMA was able to detect prostate cancer lesions that were still undetectable 6 months later with standard of care (SOC) PSMA imaging agents<sup>4</sup>.

From an imaging perspective, acquisition times were consistent across <sup>68</sup>Ga-PSMA-11 and both same-day and next-day <sup>64</sup>Cu-SAR-bisPSMA scans, with PET scans acquired for 2 minutes per bed position. At 24 hours, <sup>64</sup>Cu-SAR-bisPSMA demonstrated higher lesion uptake compared to <sup>68</sup>Ga-PSMA-11 (median maximum standardised uptake value [SUVmax] 13.6 vs. 5.3), and lower background bladder activity (median SUVmax 12.0 vs. 34.5), improving tumour-to-background contrast. These imaging attributes, which allow better visualisation of the fossa and thus detection of low volume local recurrence, likely contributed to an almost perfect agreement across the three independent blinded readers for the <sup>64</sup>Cu-SAR-bisPSMA scans, whereas the agreement was lower for <sup>68</sup>Ga-PSMA-11. This means the readers reached the same conclusions when assessing the <sup>64</sup>Cu-SAR-bisPSMA scans far more often than when assessing the <sup>68</sup>Ga-PSMA-11 scans in a blinded fashion (almost perfect level of agreement for <sup>64</sup>Cu-SAR-bisPSMA, Cohen’s Kappa 0.94 vs. 0.75 for <sup>68</sup>Ga-PSMA-11).

Importantly, these imaging findings translated into clinically meaningful changes in patient care, with a marked difference between <sup>64</sup>Cu-SAR-bisPSMA and <sup>68</sup>Ga-PSMA-11 (planned management changes observed in 44% of patients following <sup>64</sup>Cu-SAR-bisPSMA imaging). The two most common modifications in treatment plan were changes from observation to active treatment (12/22), and changes in the radiation field (9/22). Active planned management increased from 66% based on <sup>68</sup>Ga-PSMA-11 results to 90% based on <sup>64</sup>Cu-SAR-bisPSMA findings. This highlights the impact of <sup>64</sup>Cu-SAR-bisPSMA on the management of patients with BCR and low PSA levels, a population in whom SOC PSMA PET scans frequently fail to visualise prostate cancer lesions.



**Figure 1.** The 24-hour  $^{64}\text{Cu}$ -bisPSMA positive lesion in the prostate fossa (SUVmax 15) was confirmed as true positive with PSA response to fossa radiotherapy (top images, red arrow).  $^{68}\text{Ga}$ -PSMA-11 scan was reported as negative by all readers (bottom images). Images demonstrate the improved tumour-to-background activity in the prostate fossa with the bladder SUVmax significantly lower on  $^{64}\text{Cu}$ -SAR-bisPSMA images compared to  $^{68}\text{Ga}$ -PSMA-11.

The authors of the Co-PSMA publication wrote, “This is the first time that a PSMA-targeted imaging agent has demonstrated significantly improved imaging characteristics compared to those currently available, potentially marking an important step forward in imaging technology akin to that seen in the evolution from  $^{18}\text{F}$ -Choline/Flucyclovine to PSMA-targeted PET/CT”.

This leap in PET imaging technology has the potential to improve treatment decisions and outcomes in patients with biochemical results following radical prostatectomy<sup>2</sup>.

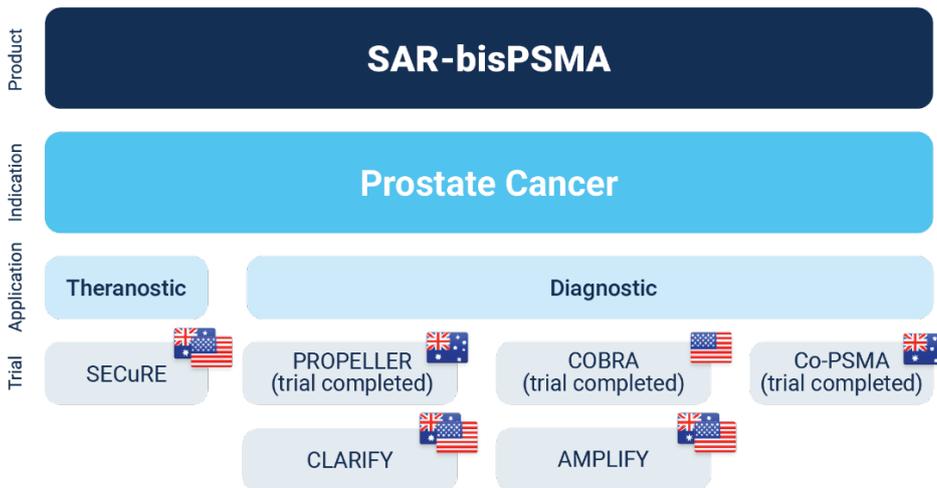
**Clarity’s Executive Chairperson, Dr Alan Taylor, commented,** “SAR-bisPSMA is an outstanding agent, developed from the benchtop of Australian science with the clinical data now gaining significant momentum as we approach commercialisation. We have seen incredible results with evidence of improved diagnostic performance under every condition we have tested the agent, from the head-to-head PROPELLER study against  $^{68}\text{Ga}$ -PSMA-11 in pre-prostatectomy patients with only same-day imaging<sup>5</sup>, to the COBRA trial<sup>4</sup> in BCR where any SOC imaging agent could have been used and participant selection criteria had no limitation on upper PSA levels (median 0.9 ng/mL, range 0.25 – 17.6), to this head-to-head Co-PSMA trial against  $^{68}\text{Ga}$ -PSMA-11 in BCR patients with low PSA (median 0.43, IQR: 0.31– 0.63). While we are still awaiting data from the registrational Phase III AMPLIFY trial<sup>6</sup> and finishing recruitment into the pivotal CLARIFY study<sup>7</sup> shortly, we are taking definitive steps towards entering the blockbuster PSMA PET market and are well prepared to better serve this patient population.

“Our team and collaborators have done the hard work and followed the highest standards of clinical research in developing this product to become the gold standard in PSMA PET imaging, and clinicians are recognising the added benefits of the improved diagnostic performance offered by  $^{64}\text{Cu}$ -SAR-bisPSMA. With our three Fast Track Designations for the one SAR-bisPSMA agent, we look forward to continuing our work with the US Food and Drug Administration (FDA) and submitting New Drug Applications (NDAs) for this product once we complete AMPLIFY and CLARIFY. Our supply and manufacturing strategy is also positioned to provide over 2 million doses of copper-64 per year at base capacity for commercial launch, which is over two times the total addressable market for PSMA PET, and we are continuing to build added capacity to facilitate efficiencies throughout the entirety of the US. Our team and collaborators are looking forward to getting  $^{64}\text{Cu}$ -SAR-bisPSMA to patients in need as soon as possible, and as always, we will continue to update the market on the progress of our programs.”

## About Co-PSMA

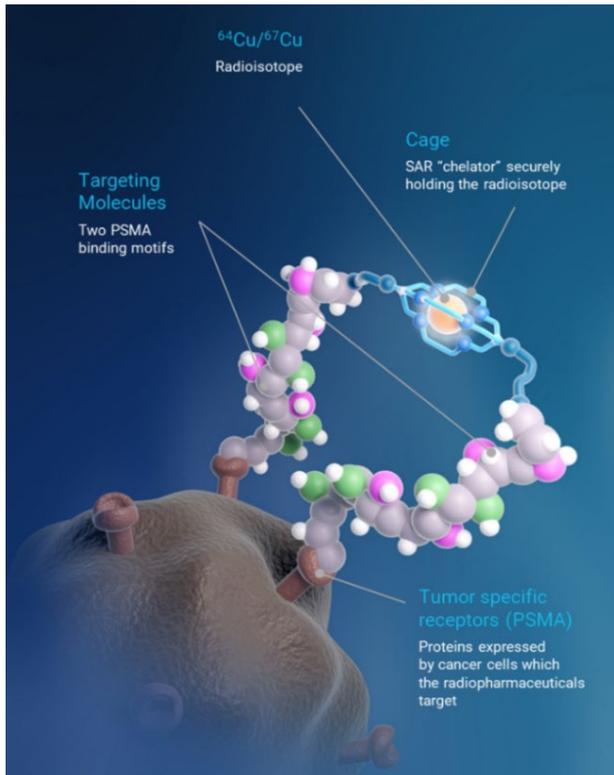
Co-PSMA (Comparative performance of <sup>64</sup>Copper [<sup>64</sup>Cu]-SAR-bisPSMA vs. <sup>68</sup>Ga-PSMA-11 PET CT for the detection of prostate cancer recurrence in the setting of biochemical failure following radical prostatectomy) was a Phase II IIT evaluating the performance of Clarity’s diagnostic product, <sup>64</sup>Cu-SAR-bisPSMA, in a head-to-head comparison to SOC <sup>68</sup>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. <sup>68</sup>Ga-PSMA-11 PET/CT was followed by <sup>64</sup>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.

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



## Disclaimer

$^{64}\text{Cu}$ -SAR-bisPSMA and  $^{67}\text{Cu}$ -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<sup>8</sup>. 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<sup>9</sup>.

## 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](http://www.claritypharmaceuticals.com)

For more information, please contact:

### Clarity Pharmaceuticals

Dr Alan Taylor

**Executive Chairperson**

[ataylor@claritypharm.com](mailto:ataylor@claritypharm.com)

Lisa Sadetskaya

**Director, Corporate Communications**

[lisa@claritypharm.com](mailto:lisa@claritypharm.com)

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