

ASX ANNOUNCEMENT

8 October 2026

## SECuRE update: recruitment target of the Cohort Expansion Main Group achieved

**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 recruitment target of the Cohort Expansion (Main Group) of the Phase I/IIa SECuRE trial has been achieved. The enrolled sixteen participants with metastatic castration-resistant prostate cancer (mCRPC) are being evaluated for the efficacy and safety of up to six cycles of 8 GBq of <sup>67</sup>Cu-SAR-bisPSMA. Recruitment remains ongoing for additional participants in the Cohort Expansion to be treated with the combination of 8 GBq <sup>67</sup>Cu-SAR-bisPSMA with enzalutamide (an androgen receptor pathway inhibitor [ARPI]).

The Cohort Expansion aims to assess the efficacy and safety of <sup>67</sup>Cu-SAR-bisPSMA in 24 mCRPC patients prior to receiving taxane or radioligand-based therapies, with or without the concomitant administration of enzalutamide (approximately 8 and 16 participants, respectively). <sup>67</sup>Cu-SAR-bisPSMA continues to demonstrate a favourable safety profile and promising efficacy in the SECuRE trial. Based on the recent data from 19 participants reported on the 5<sup>th</sup> of August 2026<sup>1</sup>, a median of 2 cycles (range: 1-4) of <sup>67</sup>Cu-SAR-bisPSMA at 8 GBq led to substantial declines in prostate-specific antigen (PSA), with 74% of evaluable participants achieving PSA25 (i.e., ≥25% reduction in PSA from baseline), 63% PSA50, 53% PSA75 and 26% PSA90. Among 16 radiographically evaluable participants treated at the 8 GBq dose level, 81% achieved disease control (50% with stable disease and 31% with complete response [assessed by Response Evaluation Criteria in Solid Tumors 1.1, RECIST] or undetectable disease [assessed by bone scan and/or PSA]). Across the entire <sup>67</sup>Cu-SAR-bisPSMA clinical development program, seven participants have achieved complete response/undetectable disease. Most related adverse events were mild or moderate and transient. More updates from the Cohort Expansion Phase will be released in the coming months as data from the most recently enrolled participants continue to mature.

**Clarity's Executive Chairperson, Dr Alan Taylor, commented,** "Our SAR-bisPSMA programs continue to generate an impressive evidence base in clinical trials and real-world case profiles. As our two registrational diagnostic trials are nearing readouts early next year, we look forward to further leveraging the benefits of the bivalent PSMA molecule as well as of the "perfect pairing" of copper isotopes to explore the positive impact our product could make in the treatment of mCRPC, an area of focus for us as we look to develop a product with key advantages over standard-of-care. Reaching the recruitment target in the Main Group of the SECuRE study is a significant milestone in the development of this promising theranostic product.

"With a total of 16 patients enrolled in the main group of the Cohort Expansion (multi-dose), as well as 21 participants treated in the Dose Escalation phase, we have observed strong efficacy with a favourable safety profile of <sup>67</sup>Cu-SAR-bisPSMA. We are inspired and motivated to progress our theranostic program as almost a third of all evaluable patients treated at the 8 GBq dose level had achieved undetectable levels of disease and/or complete response across the <sup>67</sup>Cu-SAR-bisPSMA program at the date of the last assessment (20 July 2026). While we continue to collect data from the enrolled participants and to recruit into the enzalutamide arm to explore the potential further benefits of this combination with <sup>67</sup>Cu-SAR-bisPSMA, we are already in planning for a registrational theranostic Phase III trial based on the preliminary results.

"We look forward to providing a further update on the SECuRE trial shortly as our team and collaborators continue to generate a compelling body of high-quality data, advancing SAR-bisPSMA towards commercialisation, as we believe this unique molecule could improve the outcomes for prostate cancer patients across multiple stages of disease, from accurate lesion detection in the pre-prostatectomy and biochemical recurrence (BCR) settings through to treatment in mCRPC."

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## About the SECuRE trial

The SECuRE trial ([NCT04868604](#))<sup>2</sup> is a Phase I/IIa theranostic trial for identification and treatment of participants with PSMA-expressing mCRPC using <sup>64</sup>Cu/<sup>67</sup>Cu-SAR-bisPSMA. <sup>64</sup>Cu-SAR-bisPSMA is used to visualise PSMA-expressing lesions and select candidates for subsequent <sup>67</sup>Cu-SAR-bisPSMA therapy. The trial is a multi-centre, single arm study, planning to enroll approximately 54 participants in the US. The overall aim of the trial is to determine the safety and efficacy of <sup>67</sup>Cu-SAR-bisPSMA for the treatment of prostate cancer.

The SECuRE trial consists of the Dose Escalation (Phase I) and Cohort Expansion (Phase II) Phases. Based on the data from the Dose Escalation Phase, which demonstrated a favourable safety profile and efficacy of <sup>67</sup>Cu-SAR-bisPSMA, the SECuRE trial progressed to the Cohort Expansion at an 8 GBq dose level as per the Safety Review Committee (SRC) recommendation (up to 6 cycles per patient in total)<sup>3</sup>. The Cohort Expansion Phase will include 24 participants (**Figure 1**) with a subset of participants will be treated with the combination of 8 GBq of <sup>67</sup>Cu-SAR-bisPSMA with enzalutamide (ARPI), in line with the positive results from the ENZA-p trial<sup>4</sup> and previous discussions with and advice from key global medical experts in the field of prostate cancer.

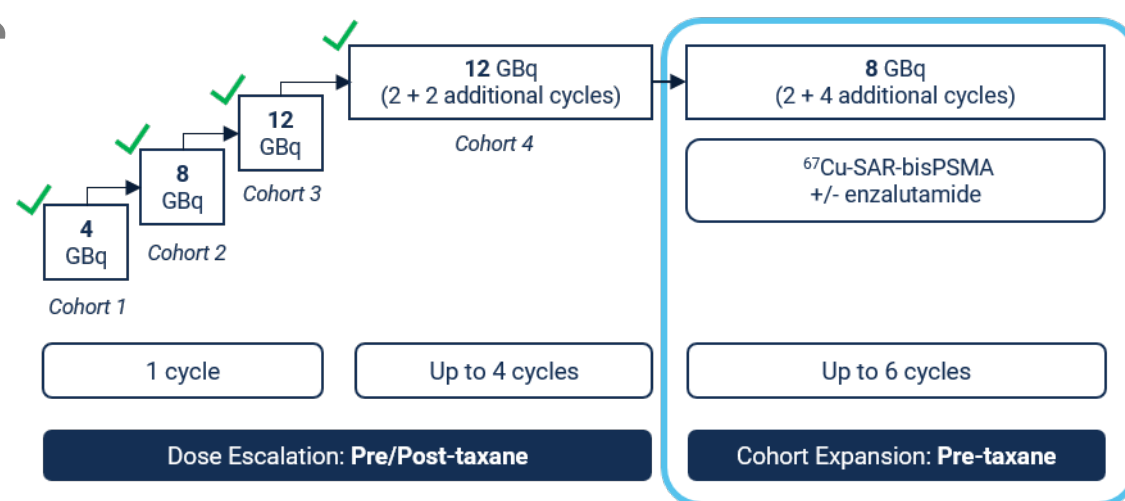
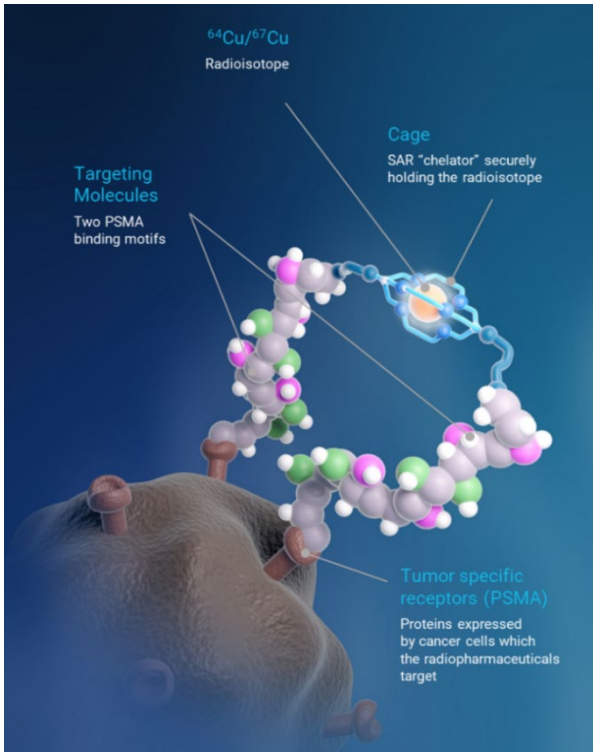


Figure 1. SECuRE study design

## 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 platform 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.

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$^{67}\text{Cu}$ -SAR-bisPSMA and  $^{64}\text{Cu}$ -SAR-bisPSMA are unregistered products. The safety and efficacy of  $^{67}\text{Cu}$ -SAR-bisPSMA and  $^{64}\text{Cu}$ -SAR-bisPSMA have 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 these products will become commercially available.

Overview of Clarity's SAR-bisPSMA clinical program

| Product     | SAR-bisPSMA                                                                                |                                                                                                                  |                                                                                                                  |                                                                                                                |
|-------------|--------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|
| Indication  | Prostate Cancer                                                                            |                                                                                                                  |                                                                                                                  |                                                                                                                |
| Application | Theranostic                                                                                |                                                                                                                  | Diagnostic                                                                                                       |                                                                                                                |
| Trial       | SECURE  | PROPELLER (results released)  | COBRA (results released)      | Co-PSMA (results released)  |
|             |                                                                                            | CLARIFY                       | AMPLIFY (recruitment closed)  |                                                                                                                |

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>5</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>6</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 TCTs based on its SAR Technology Platform for the treatment of cancers.

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

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

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