ASX ANNOUNCEMENT

15 January 2026

SECuRE trial to continue with no modifications to protocol following Safety Review Committee meeting

HIGHLIGHTS

- Following an interim data review of the Cohort Expansion Phase (Phase II) of the SECuRE trial, the Safety Review Committee (SRC) confirms the trial will continue with no modifications to the protocol.

Patient population

- With the SECuRE trial continuing to recruit, a total of nine participants who had evaluable data by the 25th of November 2025 were included in the interim assessment by the SRC, with the majority of participants receiving at least two cycles of 8 GBq of ^{67}Cu-SAR-bisPSMA each by the data cut-off date.
- Seven participants received ^{67}Cu-SAR-bisPSMA and two participants were treated with a combination of ^{67}Cu-SAR-bisPSMA with enzalutamide.
- Most participants were heavily pre-treated (with 55.6% having received more than 5 previous anti-cancer regimens) and had bone metastasis (66.7%).

Safety

- The safety profile of ^{67}Cu-SAR-bisPSMA remains favourable with most related adverse events (AEs) in the Cohort Expansion to date being Grade 1 or 2. The most common AEs were nausea and lymphopenia (observed in 33.3% of participants, for each AE).

Efficacy

- Six participants had at least two prostate specific antigen (PSA) results following ^{67}Cu-SAR-bisPSMA administration, with all showing a decrease in PSA. Of those, four participants (66.7%) thus far had a reduction of more than 50% in PSA (PSA50) and two participants (33.3%) had a reduction of more than 80% (PSA80).
- One participant who presented with bone metastasis at enrolment achieved undetectable PSA with no prostate cancer detected by computed tomography (CT) or bone scan following ^{67}Cu-SAR-bisPSMA treatment. The participant reported having excellent quality of life following the treatment.

Next Steps

- The SECuRE trial will continue enrolment into the Cohort Expansion Phase with planned completion of recruitment in 2026. Phase III registrational trial planning ongoing based on data generated to date.

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 share a number of updates on the SECuRE trial following an SRC meeting. The SRC has recommended that the trial continue with the Cohort Expansion Phase (Phase II) as planned with no modifications to the protocol. The interim results assessed by the SRC were collected from nine participants enrolled in the cohort that had evaluable data by the cut-off date of the 25th of November 2025 and continue to show promising efficacy and a favourable safety profile of ^{67}Cu-SAR-bisPSMA.

The majority of the nine participants had bone metastasis at enrolment (66.7%) and received multiple lines of previous treatments (more than 5 previous anti-cancer regimens, 55.6%). Median PSA prior to ^{67}Cu-SAR-bisPSMA treatment was 18.9 ng/mL (range 1.5-30.2 ng/mL). Six out of these nine participants received at least 2 cycles of 8 GBq of ^{67}Cu-SAR-bisPSMA each, with two of them also receiving concomitant enzalutamide.

Of the nine participants included in this SRC analysis, six had at least two PSA results following their ^{67}Cu-SAR-bisPSMA treatment by the data cut-off date. Of these six participants, thus far four (66.7%) showed reductions in PSA of 50% or more (PSA50) and two (33.3%) showed reductions of 80% or more (PSA80).

The safety profile of ^{67}Cu-SAR-bisPSMA remains favourable in the Cohort Expansion, with the majority of related AEs being Grade 1 or 2. The most common related AEs were nausea and lymphopenia (observed in three out of nine participants [33.3%], for each AE). The only AE that was Grade 3 or above was lymphopenia observed in three participants, some of whom had bone metastasis at baseline and/or had received multiple lines of therapy, including taxane and an investigational agent, prior to enrolment in the SECuRE study. There have been no overall renal toxicity or electrocardiogram (ECG) changes observed in these participants. In the combination enzalutamide arm, no new AEs (or worsening of AEs) related to ^{67}Cu-SAR-bisPSMA have been observed to date.

Trial participant with no detectable disease after 3 cycles of ^{67}Cu-SAR-bisPSMA

One of the participants in the Cohort Expansion was a 64-year-old man with bone metastases and baseline PSA of 5.4 ng/mL prior to entering the SECuRE study. Following his first cycle of ^{67}Cu-SAR-bisPSMA, this participant showed a dramatic 95.2% reduction in PSA. He went on to receive 2 more cycles of ^{67}Cu-SAR-bisPSMA and achieved undetectable PSA levels. In a follow-up bone scan and CT no metastatic disease was observed. This participant only exhibited mild (Grade 1) related AEs, most of which were gastrointestinal events, with no haematological or renal AEs observed. The participant reported having excellent quality of life following the treatment.

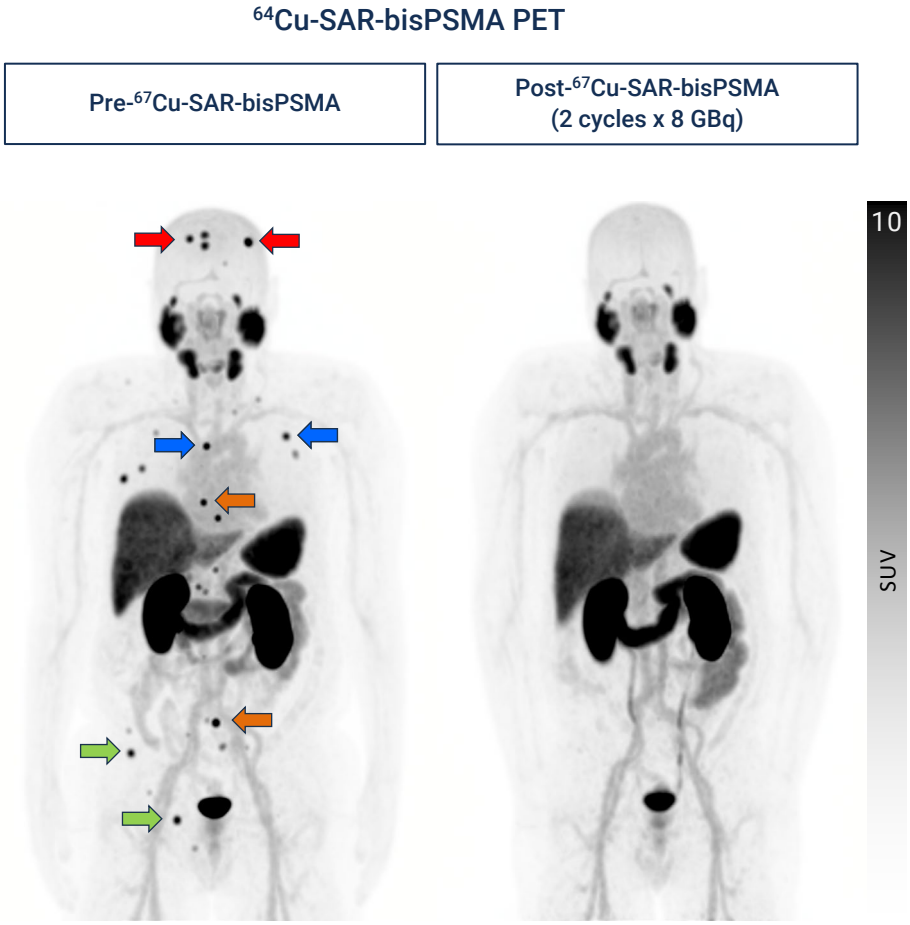


Figure 1. Lesion uptake of ^{64}Cu-SAR-bisPSMA positron emission tomography (PET) at baseline (left image) and following two cycles of ^{67}Cu-SAR-bisPSMA (8 GBq each; right image). PET image on the right was acquired 1 month after the 2nd cycle. Coloured arrows indicate representative metastatic bone lesions within each region: red – skull; blue – ribs and sternum; orange – spine; green – pelvis. Images shown as maximum intensity projections.

The interim data from this Phase II continues to confirm the favourable safety profile and promising efficacy seen in previous cohorts of the SECuRE trial[1] and supports the continuation of the trial with the aim to progress to a registrational Phase III study.

Clarity's Executive Chairperson, Dr Alan Taylor, commented, "SAR-bisPSMA continues generating world-class data in both theranostic and diagnostic trials. The combination of the optimised dimer "bis" structure with the benefits of copper isotopes, enabled by the proprietary sarcophagine technology, is proving to have created a product that is here to challenge the current treatment and diagnostic paradigms in radiopharmaceuticals.

"We have already seen a glimpse of the effects of ^{67}Cu-SAR-bisPSMA through our Dose Escalation cohorts with additional and similar data being generated in the Cohort Expansion phase, demonstrating once again excellent efficacy and safety results of ^{67}Cu-SAR-bisPSMA.

"All of the participants with evaluable data treated in the Phase II to date have shown declines in PSA, with the majority showing PSA decreases of more than 50% and mostly having only mild or moderate AEs. Most of these patients have been treated with more than 5 systemic treatment regiments and had bone metastasis prior to entering the SECuRE study. Although the number of participants with evaluable data to date is small, it is incredible to see yet another extraordinary case where a patient who had bone metastasis prior to entering the study achieved undetectable PSA following ^{67}Cu-SAR-bisPSMA treatment, with no disease observed by anatomical and molecular imaging at the last assessments. This participant only experienced mild, transient AEs, most being gastrointestinal, and has reported having excellent quality of life following the treatment.

"Importantly, the work we have undertaken during the Dose Escalation Phase is now continuing to provide a strong foundation for us as we look ahead at protocol development and dosing for our Phase III clinical trial and commercialisation. As the participant numbers continue to increase with the trial enrollment, we continue to see very promising responses over and over again, giving us more confidence about the future of this product and its potential for commercialisation in metastatic castration-resistant prostate cancer (mCRPC). With three Fast Track Designations for the SAR-bisPSMA product and positive interactions with the US Food and Drug Administration (FDA) to date, we are working towards bringing this agent to clinicians and their patients around the world through the entirety of the prostate cancer journey, from first diagnosis to late-stage disease. All of these indications, being imaging in pre-definitive therapy and biochemical recurrence, as well as therapy in mCRPC, are blockbuster markets individually for prostate-specific membrane antigen (PSMA) targeted products, with an estimated combined market value of approximately US$10-15 billion by 2030. We are committed to continuing the development of this product, aiming to bring improved diagnostic and treatment options for prostate cancer in various stages of their disease."

About the SECuRE trial

The SECuRE trial (NCT04868604)[2] is a Phase I/IIa theranostic trial for identification and treatment of participants with PSMA-expressing mCRPC using ^{64}Cu/^{67}Cu-SAR-bisPSMA. ^{64}Cu-SAR-bisPSMA is used to visualise PSMA-expressing lesions and select candidates for subsequent ^{67}Cu-SAR-bisPSMA therapy. The trial is a multi-centre, single arm, dose escalation study with a cohort expansion involving approximately 54 participants in the US. The overall aim of the trial is to determine the safety and efficacy of ^{67}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 ^{67}Cu-SAR-bisPSMA, the SECuRE trial progressed to the Cohort Expansion (Phase II) at an 8 GBq dose level as per the SRC recommendation (up to 6 cycles per patient in total)[3].

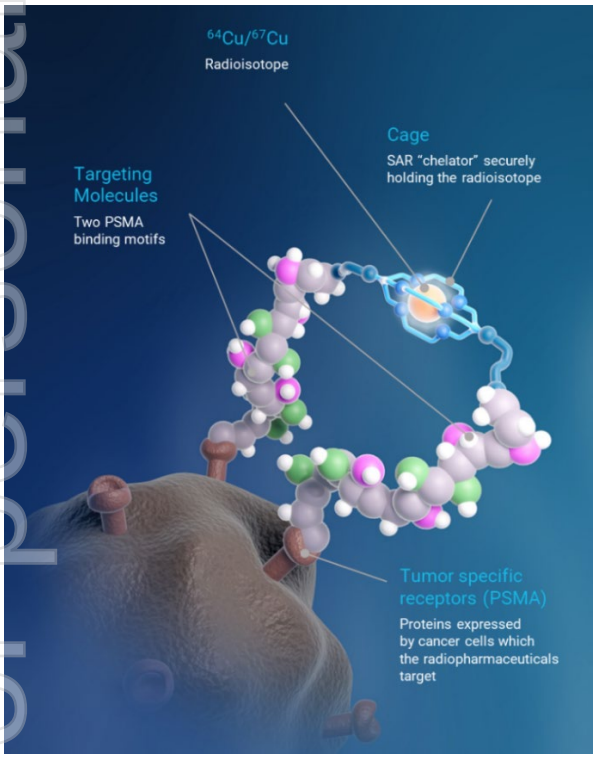
Cohort 2 of the Dose Escalation phase of the trial, where participants were dosed with 8 GBq of ^{67}Cu-SAR-bisPSMA, demonstrated a very low rate of related AEs while all three participants achieved PSA declines of 80% or more

(PSA80)[1]. The Dose Escalation Phase also showed high PSA response rates of the mCRPC in the pre-chemotherapy setting with a favourable safety profile: 92% of pre-chemotherapy participants (12/13) demonstrated PSA drops greater than 35%, PSA reductions greater than 50% were reached in 61.5% (8/13) of participants, and reductions of 80% or more were achieved in 46.2% (6/13) of participants[1]. These results supported the progress of the trial to its Cohort Expansion Phase using 8 GBq multi-dose in participants who had not received chemotherapy in the mCRPC setting.

Recruitment is currently ongoing into the Cohort Expansion Phase which will include 24 participants. A subset of participants will be treated with the combination of 8 GBq of ^{67}Cu-SAR-bisPSMA with enzalutamide (androgen receptor pathway inhibitor [ARPI]), in line with the positive results from the Enza-p trial[4] and previous discussions with and advice from key global medical experts in the field of prostate cancer, including the Company's Clinical Advisory Board members, Prof Louise Emmett and Prof Oliver Sartor, as well as the SRC.

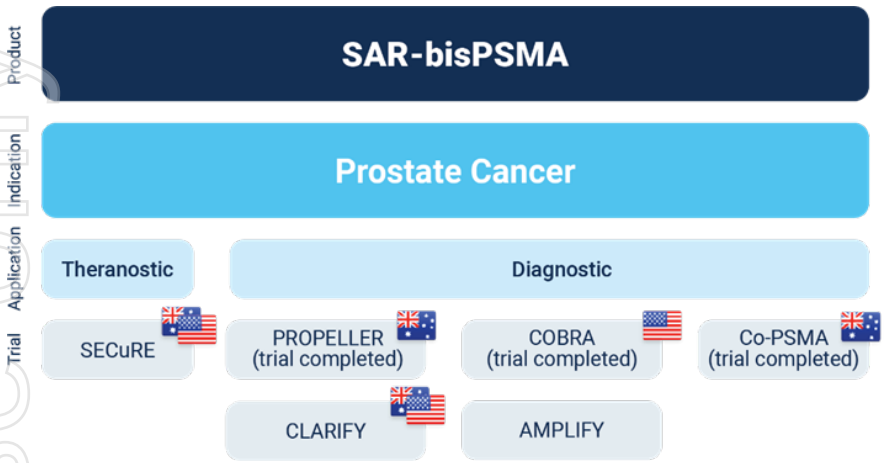
About SAR-bisPSMA

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.



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

Overview of Clarity's SAR-bisPSMA clinical program



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[5]. 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[6].

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.

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