ASX ANNOUNCEMENT

5 August 2026

SECuRE update: 8 GBq ^{67}Cu-SAR-bisPSMA dose level with two additional complete responses

HIGHLIGHTS

Preliminary assessment of the 8 GBq ^{67}Cu-SAR-bisPSMA dose cohorts

- Nineteen participants from the SECuRE trial (NCT04868604)[1] were included in this assessment of the safety and efficacy of the 8 GBq ^{67}Cu-SAR-bisPSMA dose level. This includes 3 participants from cohort 2 of the Dose Escalation phase and 16 participants from the ongoing Cohort Expansion phase (data cut-off: July 20, 2026). The SECuRE trial continues to recruit new and treat existing participants in the Cohort Expansion phase.
- Prostate-specific antigen (PSA) declines were substantial with 74% of evaluable participants at data cut-off achieving PSA25 (i.e. reductions of ≥25% in PSA), 63% PSA50, 53% PSA75 and 26% PSA90. Responses continue to mature in participants remaining on treatment.
- A total of 81% (n=13) of the evaluable participants for radiographic assessment at data cut-off (n=16) achieved disease control (50% [n=8] stable disease and 31% [n=5] complete response/undetectable disease).
- Across all 19 participants, the median number of treatment cycles of 8 GBq ^{67}Cu-SAR-bisPSMA was two (range: 1-4), with average cycles per participant being 2.1±1.0 (standard deviation, SD) as of data cut-off date.
- Most participants had bone metastases (63%) and were exposed to multiple lines of therapy, with 79% having received 5 or more previous anti-cancer regimens, prior to being enrolled in the SECuRE trial.
- The most common related adverse events (AEs) were gastrointestinal and haematological disorders, with the majority being mild or moderate (Grade 1/2) and transient. The prevalence and severity of related AEs observed in this group of participants were generally lower compared to the overall trial population.

Complete response/undetectable disease

- Two new participants that were evaluable at data cut-off in the Cohort Expansion phase of the SECuRE trial achieved a complete response as assessed by Response Evaluation Criteria in Solid Tumors 1.1 (RECIST, included in the above complete response count).
- This brings the total number of participants who have achieved a complete response (assessed by RECIST) or undetectable disease (assessed by bone scan and/or PSA) across the ^{67}Cu-SAR-bisPSMA program to seven, five of whom were from the 8GBq dose cohorts, based on the most recent clinical assessments.

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.

Preliminary assessment of the 8 GBq ^{67}Cu-SAR-bisPSMA dose cohorts

Patient population

The SECuRE trial is currently recruiting in the Cohort Expansion phase at the 8 GBq ^{67}Cu-SAR-bisPSMA dose level (up to 6 doses). This preliminary efficacy and safety assessment includes all trial participants who received 8 GBq treatment cycles, comprising 16 participants from the ongoing Cohort Expansion phase and 3 participants from cohort 2 of the Dose Escalation phase (19 participants in total), by the data cut-off of 20 July 2026.

Most participants had bone metastases (63%) and had received multiple lines of therapy prior to being enrolled in the trial (79% received 5 or more previous anti-cancer regimens). Previous standard treatments included androgen deprivation therapy (ADT), radiation, first- and/or second-generation androgen receptor pathway inhibitor (ARPI), with some participants having received taxane-based therapy for metastatic hormone-sensitive disease. Some participants were exposed to an experimental prostate-specific membrane antigen (PSMA) T-Cell Engager prior to their enrolment into the SECuRE study. The median number of treatment cycles of ^{67}Cu-SAR-bisPSMA across participants was two (range: 1-4, mean 2.1±1.0 [SD]). Three of these participants from the Cohort Expansion phase were treated with concomitant enzalutamide.

PSA and radiographic assessments

A substantial reduction in PSA was observed, with 74% (n=14) of participants achieving a PSA25 response (i.e. reductions of ≥25% in PSA), 63% (n=12) PSA50, 53% (n=10) PSA75, and 26% (n=5) PSA90 (**Figure 1**).

A total of 81% (n=13) of the participants who were evaluable for radiographic assessment (n=16) achieved disease control. This includes 50% (n=8) with stable disease and 31% (n=5) with complete response/undetectable disease (as assessed by RECIST and/or bone scan.

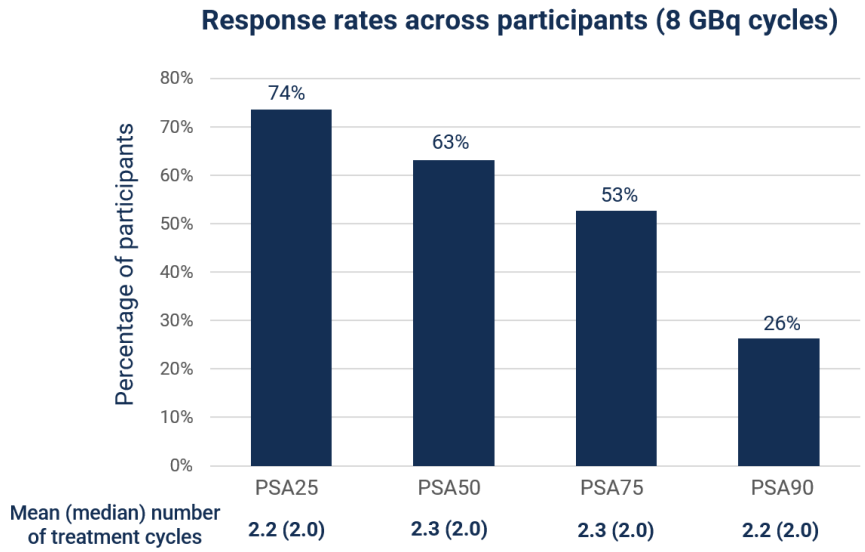


Figure 1. PSA responses of participants from cohort 2 (N=3) and Cohort Expansion (N=16) who received 1-4 doses of 8 GBq of ^{67}Cu-SAR-bisPSMA as of 20 July 2026.

Safety profile

Participants who received 8 GBq cycles, including those in the Cohort Expansion Phase, generally developed a lower prevalence and severity of related AEs compared to the overall trial population. The most frequently reported related AEs were dry mouth and nausea, each occurring in 9 (47%) and 8 (42%) participants, respectively. Anaemia and decreased neutrophil count were each reported in 4 (21%) participants, while fatigue was reported in 5 (26%) participants. Most events were low grade (mild/moderate) and transient, with two Grade 3 events (lymphocyte and white blood cell count decreases) in 1 (5%) participant. No Grade ≥4 related events were reported.

Complete response/undetectable disease observed in seven participants in the ^{67}Cu-SAR-bisPSMA program

Two new participants in the Cohort Expansion phase of the SECuRE trial who were evaluable at data cut-off achieved complete response as assessed by RECIST. Combined with the five previously announced cases[2,3,4,5], this brings the total number of participants who achieved complete response or undetectable disease (assessed by RECIST, bone scan and/or PSA) across the ^{67}Cu-SAR-bisPSMA program to seven. Five out of these seven participants received treatment at the 8 GBq ^{67}Cu-SAR-bisPSMA dose level. This represents almost a third (31%) of all participants evaluable for radiographic assessment treated at the 8 GBq ^{67}Cu-SAR-bisPSMA dose level.

The median baseline PSA among these seven participants was 90.3 ng/mL (range 3.3 – 490.3). They had received a median of 5 prior anti-cancer regimens (range 4-7). Bone metastases were present in four of seven participants (57%). Among the participants who had received 8 GBq doses, the median number of cycles was 3 (range 1-4, mean 2.8±0.8 [SD]). All seven participants had received prior second-generation ARPI.

These observations demonstrate considerable anti-tumour activity of ^{67}Cu-SAR-bisPSMA following a small number of 8 GBq treatment cycles in metastatic castration-resistant prostate cancer (mCRPC) patients who have failed multiple lines of therapy.

Clarity's Executive Chairperson, Dr Alan Taylor, commented, "The SAR-bisPSMA product continues to generate an impressive body of evidence in clinical trials and case studies, highlighting the strength of the evidence in both diagnostic and theranostic applications.

"Most impressively, despite the relatively small numbers of patients enrolled in the SECuRE trial to date, and most having received up to 2 treatment cycles at 8 GBq, we see a trend that is impossible to ignore. We continue seeing patients with mCRPC, who have gone through numerous lines of therapy prior to the SECuRE study enrolment, achieve undetectable disease and/or complete response following ^{67}Cu-SAR-bisPSMA treatment. Seven participants have now achieved undetectable disease and/or complete response across all cohorts (assessed by RECIST, bone scan and/or PSA), and five of these are from the 8 GBq cohorts. This means that almost a third of all evaluable patients treated at this dose level have achieved a complete response and/or undetectable disease.

"The evidence of the depth and consistency of responses achievable with ^{67}Cu-SAR-bisPSMA is further substantiated by the PSA responses across the SECuRE study in patients who received their ^{67}Cu-SAR-bisPSMA treatments at the 8 GBq dose level. PSA reductions of ≥50% are currently at 63%, with over a quarter of patients reaching PSA90. Importantly, ^{67}Cu-SAR-bisPSMA at the 8 GBq dose level shows a favourable safety profile, with AEs being mostly mild to moderate and transient. This highlights the potential of this therapy in earlier stages of disease, aiming to help improve treatment outcomes of a broader prostate cancer patient population.

"The SECuRE trial will continue enrolment into the Cohort Expansion Phase with Phase III registrational trial planning ongoing based on data that continues to be generated.

"The benefits we are seeing in the clinic, based on the treatment responses and favorable safety profile achieved with so few doses, are due to our unique combination of the optimised bivalent "bis" structure with the advantages

offered by the beta emitter, copper-67, enabled by the proprietary sarcophagine (SAR) chelating technology. Time and time again we are seeing the benefits of this approach across both the diagnostic and therapeutic areas with this one molecule, from early detection in pre-prostatectomy patients to visualisation of biochemically recurrent prostate cancer and then to the treatment of mCRPC patients. Armed with the growing body of high-quality data, our team and collaborators continue to advance SAR-bisPSMA towards the paradigm shift it could bring to the prostate cancer space, aiming to improve the outcomes of so many patients with prostate cancer across multiple stages of their disease."

About the SECuRE trial

The SECuRE trial (NCT04868604)[1] 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 study, planning to enroll 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 at an 8 GBq dose level as per the Safety Review Committee (SRC) recommendation (up to 6 cycles per patient in total)[3]. Recruitment is currently ongoing for the Cohort Expansion Phase which will include 24 participants (**Figure 2**). A subset of participants will be treated with the combination of 8 GBq of ^{67}Cu-SAR-bisPSMA with enzalutamide (ARPI), in line with the positive results from the Enza-p trial[6] and previous discussions with and advice from key global medical experts in the field of prostate cancer.

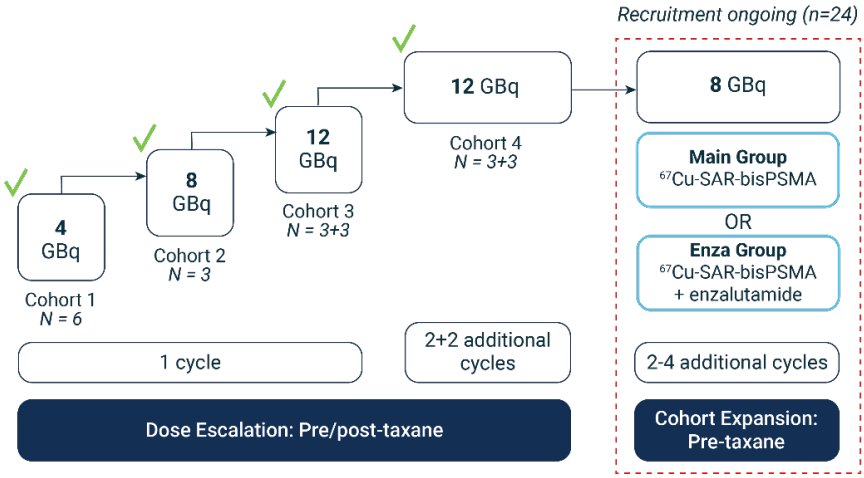
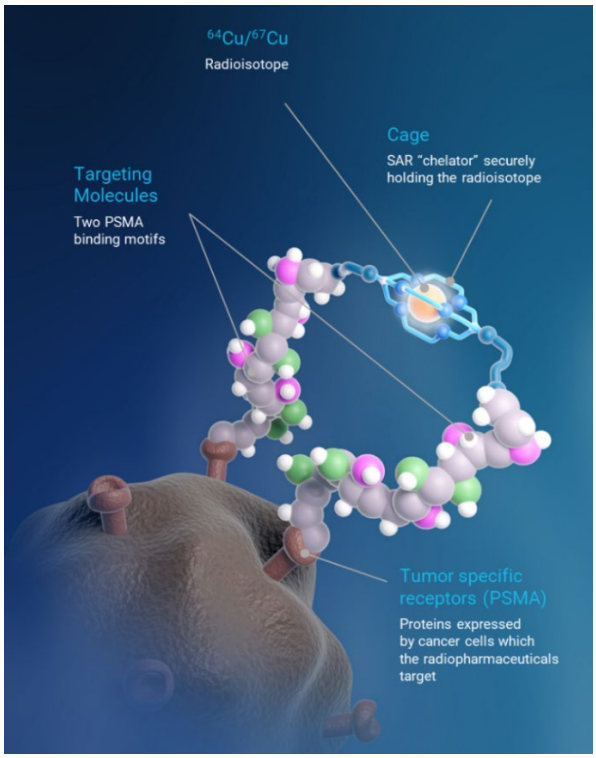


Figure 2. SECuRE study design

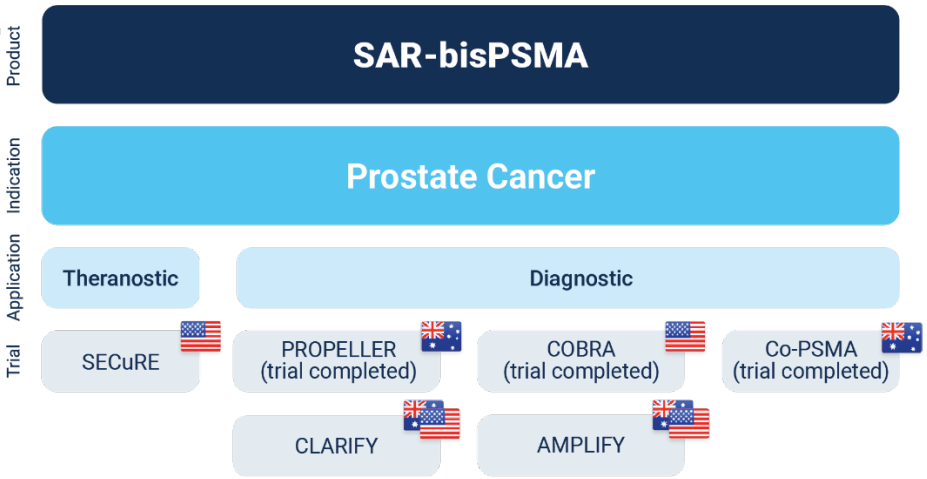
About SAR-bisPSMA

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 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 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



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[7]. 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[8].

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.