

ASX ANNOUNCEMENT

10 March 2026

Registrational Phase III AMPLIFY trial: Target number of participants 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 Phase III AMPLIFY trial (NCT06970847)¹ has now consented in excess of the planned number of participants following strong demand for study participation at sites in the United States (US) and Australia. Consenting of new patients has stopped at all sites pending completion of remaining screening assessments and confirmation of final enrolment numbers.

AMPLIFY (⁶⁴Cu-SAR-bisPSMA Positron Emission Tomography: A Phase 3 Study of Participants with Biochemical Recurrence of Prostate Cancer) is a non-randomised, single-arm, open-label, multi-centre, diagnostic clinical trial of ⁶⁴Cu-SAR-bisPSMA positron emission tomography (PET) in participants with rising or detectable prostate-specific antigen (PSA) after initial definitive treatment at clinical sites across the US and Australia.

The aim of this registrational study is to investigate the diagnostic ability of ⁶⁴Cu-SAR-bisPSMA PET/computed tomography (CT) to detect recurrence of prostate cancer in men with PSA levels above 0.2 ng/mL. Evaluation will be across two imaging timepoints: Day 1 (1-4 hours post-administration, same-day imaging) and Day 2 (approximately 24 hours post administration, next-day imaging).

AMPLIFY commenced in May 2025, seeking to enrol approximately 220 participants, and the first trial participant was imaged in the same month at Xcancer with Dr Luke Nordquist (Omaha, NE). The data from this study will complement the Phase I/II COBRA² and Phase II Co-PSMA³ trials. Both studies have demonstrated enhanced imaging capabilities of ⁶⁴Cu-SAR-bisPSMA over standard-of-care (SOC) prostate-specific membrane antigen (PSMA) PET imaging in patients with biochemical recurrence (BCR) of prostate cancer. As a pivotal trial, the final study results from AMPLIFY are intended to provide evidence to support an application to the US Food and Drug Administration (FDA) for approval of ⁶⁴Cu-SAR-bisPSMA as a new diagnostic imaging agent in BCR of prostate cancer.

⁶⁴Cu-SAR-bisPSMA is also currently being evaluated in another registrational Phase III trial, CLARIFY (NCT06056830)⁴, which is expected to close recruitment in CY2026. Building on the Phase I PROPELLER⁵ study, the objective of CLARIFY is to assess the diagnostic performance of ⁶⁴Cu-SAR-bisPSMA PET across same-day and next-day imaging in detecting prostate cancer within the pelvic lymph nodes in patients who are scheduled to undergo radical prostatectomy and pelvic lymph node dissection. The CLARIFY results are intended to support an FDA approval application for ⁶⁴Cu-SAR-bisPSMA in prostate cancer patients who are candidates for definitive therapy.

Dr Alan Taylor, Executive Chairperson of Clarity Pharmaceuticals, commented, “We are about to enter the realm of a select few Australian companies who have developed a drug at the benchtop of Australian science and completed an international Phase III clinical trial with that drug, taking us one step closer to commercialisation. Our team is excited to have reached this initial recruitment milestone in the AMPLIFY trial in just 9 months since we imaged our first participant in the study. This is no small feat, given we achieved this phenomenal pace of recruitment despite three SOC products already in the market, commercialised by four different companies.

“True to our commitment to the highest standards of clinical research, we recruited participants at numerous different sites across the US and Australia to ensure the trial reflected the broad patient population, real-world clinical settings and various PET cameras in which this product is intended to be used. This strategy required careful planning to allow for all participating sites to contribute to the recruitment, based on allocation of participant numbers to be enrolled per site, resulting in what we believe will be a robust and well-balanced dataset and supporting the integrity and quality of the AMPLIFY study.

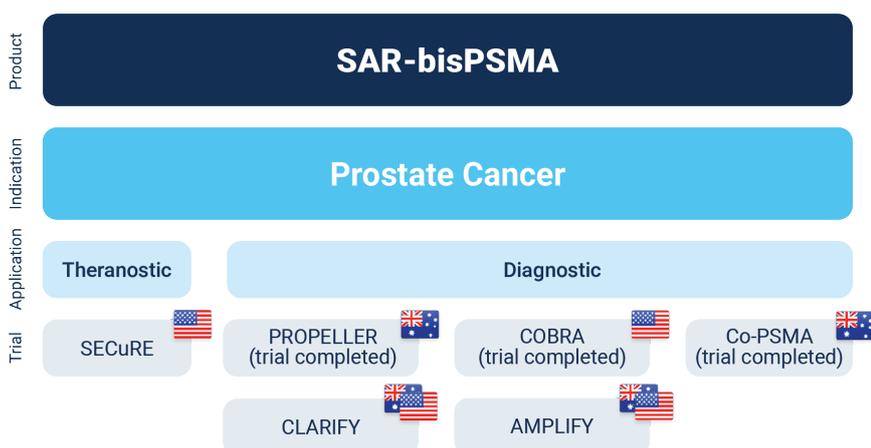
“Despite the variations in the sites’ activation times, the speed of enrolment in this trial not only highlights the unmet need in the BCR space but also indicates the strong demand for ⁶⁴Cu-SAR-bisPSMA from clinicians and patients seeking more effective and accurate prostate cancer detection diagnostics. With persistent outreach from participating sites to enrol more patients, clinicians and patients would rather use an unapproved product, undertaking additional demands of a clinical trial, than rely on the findings of the current SOC PSMA PET.

“To date, we have imaged approximately 600 patients with prostate cancer with ⁶⁴Cu-SAR-bisPSMA, and just in the last year we scanned over 350 of them. The growing demand for better imaging is driven by so many men around the world with prostate cancer who seek accurate and timely identification of disease location and recurrence. We are committed to answering these needs of patients, clinicians and imaging facilities with a next-generation diagnostic imaging agent specifically designed to deliver significant benefits in efficacy, clinical management, quality of life and operational flexibility across the prostate cancer care pathway.

“The results on ⁶⁴Cu-SAR-bisPSMA generated to date, from our initial discovery and pre-clinical work, to the recently announced Co-PSMA and the COBRA trials, constitute an extensive body of evidence against SOC, demonstrating that maximal clinical benefit of PSMA PET can be derived through the combination of the proprietary SAR-bisPSMA agent and optimised imaging timepoints facilitated by the half-life of copper-64. Achieving a two to three times improvement in lesion detection over SOC in BCR is an incredible achievement. We believe we can grow the blockbuster PSMA PET market even further with a product that has shown impressive efficacy in clinical trials coupled with many logistical and supply chain benefits. Our team will be working closely with our vendors and participating sites to advance the final data package and with regulatory authorities to get this product to patients in need as soon as possible.

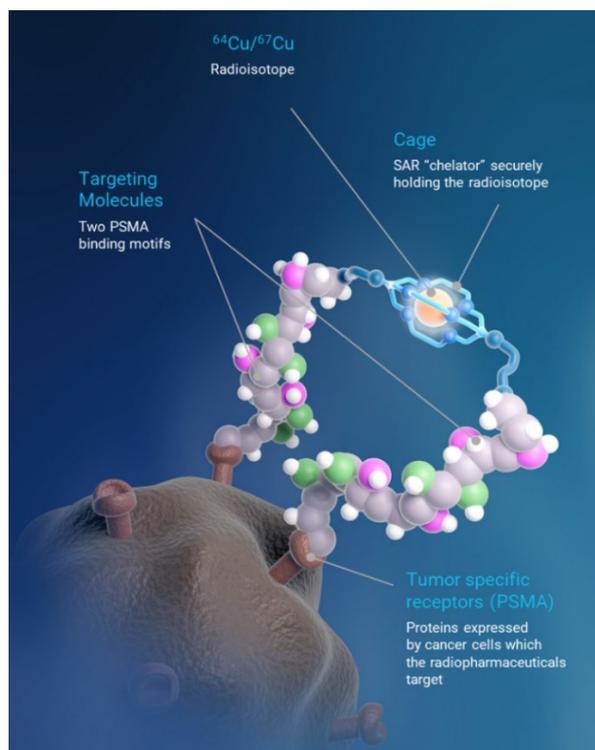
“We also look forward to closing recruitment in the CLARIFY trial this year and progressing our theranostic Phase I/IIa SECuRE trial towards completion. Together with three Fast Track Designations we have for SAR-bisPSMA and positive interactions with the US FDA to date, these milestones place us closer than ever to commercialisation of this exciting agent through the entirety of the prostate cancer journey, from first detection to late-stage metastatic disease.”

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 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 ⁶⁴Cu) for imaging and copper-67 (Cu-67 or ⁶⁷Cu) for therapy.



Disclaimer

⁶⁴Cu-SAR-bisPSMA and ⁶⁷Cu-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 these products 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 worldwide⁶. 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 disease⁷.

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