For personal use only

ASX ANNOUNCEMENT

27 October 2026

Registrational Phase III CLARIFY 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 registrational Phase III CLARIFY trial (NCT06056830)[1] has dosed the planned target of 383 participants in the study.

CLARIFY (Positron Emission Tomography Using ^{64}Cu-SAR-bisPSMA in Participants With High-risk Prostate Cancer Prior to Radical Prostatectomy: A Prospective, Single-arm, Multi-center, Blinded-review, Phase 3 Diagnostic Performance Study) is the first Phase III registrational trial for Clarity, being conducted in the United States (US) and Australia. It is a non-randomised, open-label study of ^{64}Cu-SAR-bisPSMA in participants with untreated, histopathology-confirmed prostate cancer with high-risk features who are proceeding to radical prostatectomy (removal of the prostate) with pelvic lymph node dissection (removal of lymph nodes from the pelvic region).

The primary endpoints of the study are the sensitivity and specificity of ^{64}Cu-SAR-bisPSMA to detect prostate cancer within the pelvic lymph nodes compared to the standard of truth (histopathology), assessed independently for Day 1 (1-4 hours post-administration, same-day imaging) and Day 2 (approximately 24 hours post-administration, next-day imaging). CLARIFY builds on the findings from the Phase I PROPELLER study (first-in-human multi-centre trial involving 30 participants). The study demonstrated improved diagnostic performance of same-day ^{64}Cu-SAR-bisPSMA positron emission tomography (PET) compared to ^{68}Ga-PSMA-11 PET in the pre-prostatectomy setting, including approximately 30% greater lesion detection, 2-3 times higher tracer uptake and contrast as well as higher proportion of participants with more lesions identified by ^{64}Cu-SAR-bisPSMA vs. ^{68}Ga-PSMA-11 (73% vs. 27%, respectively; average across readers for participants with discordant lesion findings; **Figures 1 and 2**)[2]. The improved diagnostic performance of next-day vs. same-day ^{64}Cu-SAR-bisPSMA PET observed in the COBRA and Co-PSMA trials in biochemical recurrence (BCR) supports the hypothesis that next-day imaging may also offer incremental benefits in the pre-prostatectomy setting, to be assessed in the CLARIFY study.

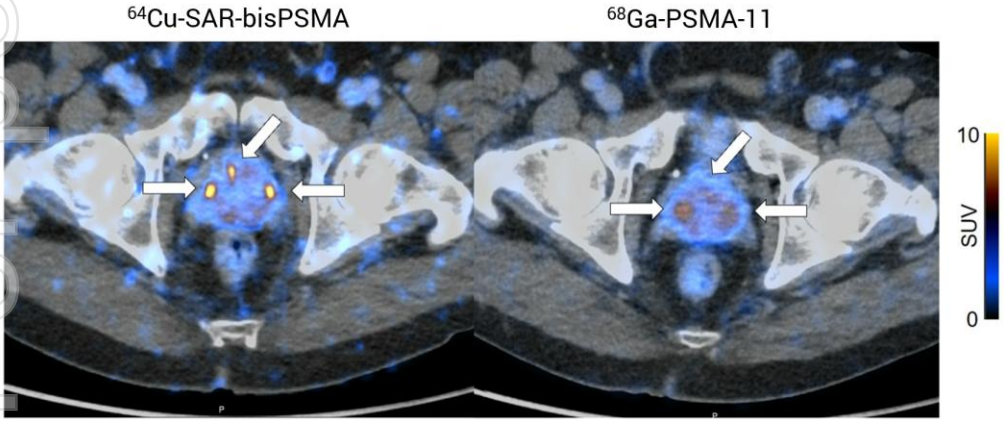


Figure 1. Intra-individual concordant lesion comparison of PSMA PET/computed tomography (CT) between ^{64}Cu-SAR-bisPSMA (left image) and ^{68}Ga-PSMA-11 (right image). The same participant is shown with concordant intraprostatic lesions indicated by white arrows, illustrating greater lesion conspicuity and tracer uptake with ^{64}Cu-SAR-bisPSMA.

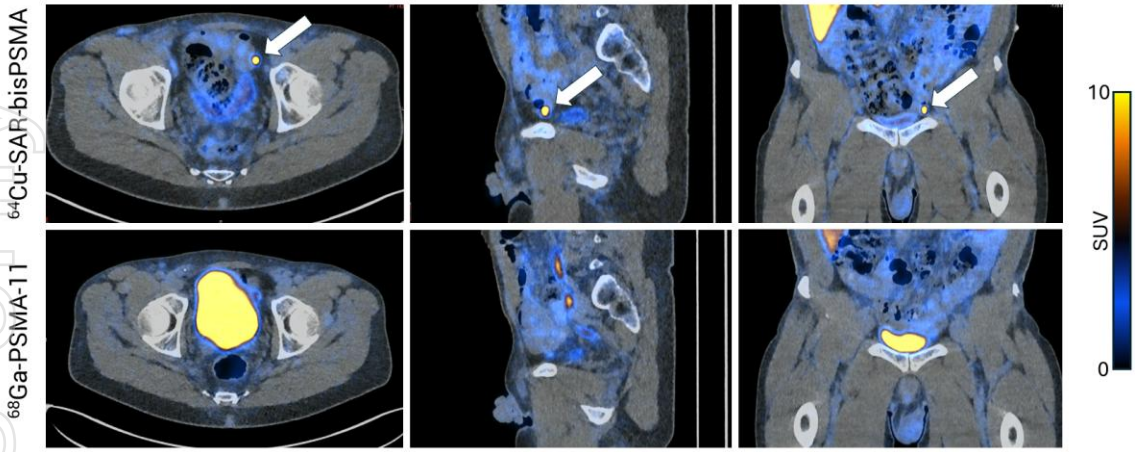


Figure 2. ^{64}Cu-SAR-bisPSMA and ^{68}Ga-PSMA-11 PET/CT images of a participant demonstrating difference in pelvic lymph node detection. One pelvic lymph node (6 mm in size) in the left pelvic region was detected by both readers on ^{64}Cu-SAR-bisPSMA scan (arrow; top images) but not on the ^{68}Ga-PSMA-11 scan (bottom images). This lesion was later confirmed as prostate cancer via histopathology.

Topline data from the CLARIFY trial are anticipated to be released in the first half of calendar year 2027, along with topline results from the AMPLIFY trial, which is investigating ^{64}Cu-SAR-bisPSMA in patients with BCR of prostate cancer[3]. As a pivotal trial, the final CLARIFY study results are intended to provide sufficient evidence to support an application to the US Food and Drug Administration (FDA) for approval of ^{64}Cu-SAR-bisPSMA as a new diagnostic imaging agent in prostate cancer patients prior to undergoing definitive therapy.

Dr Alan Taylor, Executive Chairperson of Clarity Pharmaceuticals, commented, "This milestone is a significant achievement from our team and collaborators as we progress our optimised ^{64}Cu-SAR-bisPSMA product towards trial completion and subsequent US FDA New Drug Application (NDA) submission. We now have two registrational Phase III trials with ^{64}Cu-SAR-bisPSMA that have successfully completed recruitment and are in the process of patient follow-up, in line with the trials' protocols. We look forward to the upcoming data readout from CLARIFY outlining the sensitivity and specificity of our ^{64}Cu-SAR-bisPSMA product.

"The development of ^{64}Cu-SAR-bisPSMA aims to address a significant gap in patient care for the accurate initial staging of prostate cancer (CLARIFY trial) and detection of recurrent disease (AMPLIFY trial). Currently approved prostate-specific membrane antigen (PSMA) PET agents have reported sensitivities of 27%-40%, according to their respective Phase III pivotal studies, based on the detection of pelvic lymph node metastases prior to prostatectomy (verified by histopathology)[4-9]. Importantly, none of these agents achieved the prespecified primary endpoint thresholds for sensitivity in their respective pivotal trials [4-9]. This means that the currently approved PSMA PET agents did not detect prostate cancer in the pelvic lymph nodes in more than half of the study participants in whom such metastases were confirmed by histopathology. We believe that this substantial limitation in sensitivity warrants the development of next-generation products that provide greater diagnostic confidence to clinicians and support more informed management of patients with prostate cancer.

"^{64}Cu-SAR-bisPSMA has demonstrated higher diagnostic performance with increased product uptake compared to standard-of-care (SOC) PSMA PET agents in clinical trials to date[2,10-11]. This improvement is enabled by our innovative, science-driven approach where we optimised the product with a bivalent bisPSMA molecule and explored next-day imaging benefits, made possible by the proprietary SAR Technology and the half-life of copper-64. With strong data supporting the development of ^{64}Cu-SAR-bisPSMA, we believe this product has the potential to overcome the shortcomings of the current-generation PSMA PET and improve outcomes for patients with prostate cancer.

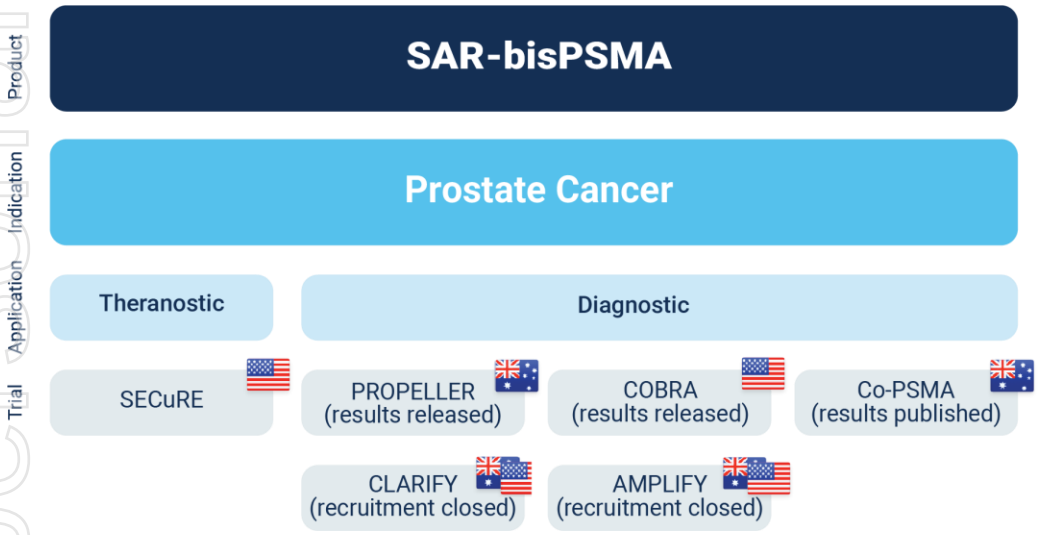
"What is most important about the CLARIFY trial is that this study is the first to determine the sensitivity and specificity of our SAR-bisPSMA product, based on the appropriate assessment of true positive, true negative, false positive and false negative lesions that can only be determined accurately using histopathology specimens (in this

For personal use only

case, pelvic lymph nodes that are surgically removed during prostatectomy). Utilising similar principles in study design to those previously used by other PSMA imaging agents on the market for their respective registrational Phase III studies, CLARIFY will provide sensitivity and specificity estimates for same-day and next-day imaging, as well as have direct comparative data to SOC PSMA imaging where SOC PET was undertaken. As sensitivity and specificity are fundamental measures of a diagnostic test's accuracy and are of high clinical importance, this trial will provide clinicians with valuable information through direct comparisons of those parameters across imaging timepoints and against real-world SOC PSMA imaging. Having the most accurate diagnostic information is essential for clinicians to determine the best course of treatment for their patients. Such treatment pathways may be quite distinct, including the removal of the prostate, with considerable long-lasting morbidities in some cases, or other more conservative approaches, personalised to each patient and potentially preserving quality of life post-treatment.

"As we move closer towards product launch, we look forward to making ^{64}Cu-SAR-bisPSMA available to the patients who need it most. We hope this will represent a paradigm shift in management of prostate cancer through improved accuracy for the detection of disease, while making radiopharmaceuticals more accessible through centralised product manufacture and broad distribution to any imaging centre with a PET camera, with flexibility in the timing of the scan."

Overview of Clarity's SAR-bisPSMA clinical trial program

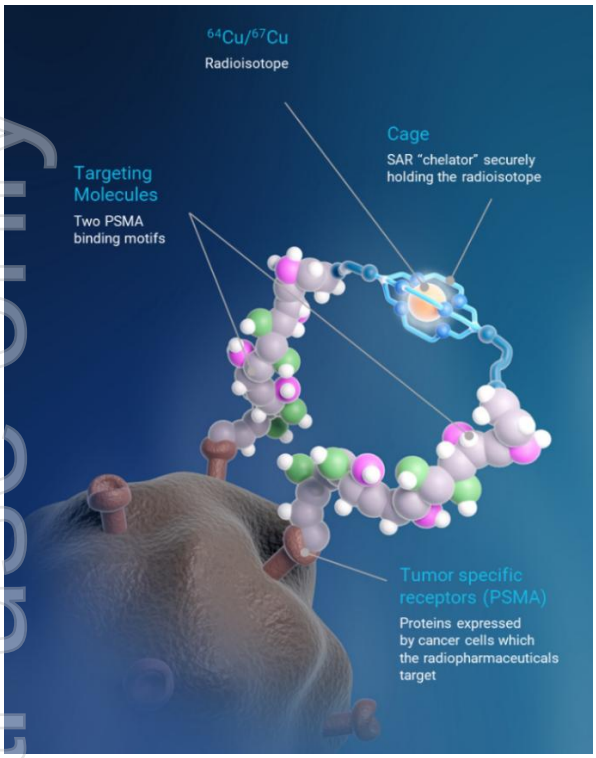


About SAR-bisPSMA

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

For personal use only

For personal use only



Disclaimer

^{64}Cu-SAR-bisPSMA and ^{67}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 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 worldwide[12]. 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[13].

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

For more information, please contact:

Clarity Pharmaceuticals

Dr Alan Taylor
Executive Chairperson
ataylor@claritypharm.com

Lisa Sadetskaya
Director, Corporate Communications
lisa@claritypharm.com

References

1. ClinicalTrials.gov Identifier: NCT06056830. https://clinicaltrials.gov/study/NCT06056830
2. Veronica Wong, Nat Lenzo, Michelle Parker and Louise Emmett. ^{64}Cu-SAR-bisPSMA (PROPELLER) positron emission tomography (PET) imaging in patients with confirmed prostate cancer. JCO 41, 5039-5039(2023). DOI:10.1200/JCO.2023.41.16_suppl.5039
3. ClinicalTrials.gov Identifier: NCT06970847. https://clinicaltrials.gov/study/NCT06970847
4. Gallium Ga 68 gozetotide injection. Prescribing Information. UCLA Biomedical Cyclotron Facility; 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/212642s002lbl.pdf
5. Hope T, et al., JAMA Oncol. 2021;7;(11):1635-1642
6. PYLARIFY TRUVU® (piflufolastat F 18) prescribing information. FDA; 2026. https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/220089Orig1s000lbl.pdf
7. Pienta KJ, et al. J Urol. 2021;206(1):52-61
8. POSLUMA® (flotufolastat F 18) prescribing information. FDA; 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216023s000lbl.pdf
9. Surasi DS, el al. Eur Urol 2023;84:361-370
10. Khan et al. Prospective Comparison of ^{64}Copper [^{64}Cu]SAR-bisPSMA vs ^{68}Gallium[^{68}Ga] PSMA-11 PET/CT for Biochemical Recurrence of Prostate Cancer Following Radical Prostatectomy (Co-PSMA Trial). Eur Urol. 2026 Jun;89(6):512520. doi: 10.1016/j. eururo.2026.03.001. PMID: 41904043
11. Nordquist et al. COBRA: Assessment of safety and efficacy of ^{64}Cu-SAR-bisPSMA in patients with biochemical recurrence of prostate cancer following definitive therapy. EANM, 2024
12. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.21660
13. American Cancer Society: Key Statistics for Prostate Cancer. https://www.cancer.org/cancer/prostate-cancer/about/key-statistics.html

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

For personal use only