ASX ANNOUNCEMENT

28 January 2025

Clarity to present COBRA and CLARIFY abstracts at two world-leading conferences

Highlights

- Two abstracts on Clarity's diagnostic COBRA and CLARIFY trials with ^{64}Cu-SAR-bisPSMA have been accepted for presentation at the American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU) 2025.
- An abstract on the COBRA study has also been selected for presentation at the American Urological Association (AUA) Annual Meeting 2025.
- The data to be presented shows that ^{64}Cu-SAR-bisPSMA identifies more lesions and at earlier timepoints than currently approved prostate-specific membrane antigen (PSMA) positron emission tomography (PET) agents, and with a high true positivity rate based on histopathology assessment. Lesions <5 mm in size were identified by ^{64}Cu-SAR-bisPSMA in 14% of participants (including lesions in the 2 mm range).
- The early identification and detection of lesions can inform treatment selection and impact the outcomes for prostate cancer patients.

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 children and adults with cancer, is pleased to announce the acceptance of two abstracts for presentation at the ASCO GU 2025 Conference on Clarity's COBRA and CLARIFY trials and an abstract on the COBRA trial at the AUA Annual Meeting 2025. These conferences are among the world's most prestigious in oncology and urology, and the acceptance of these abstracts is testament to the strength of Clarity's data and the exciting prospects for the diagnostic ^{64}Cu-SAR-bisPSMA to change the paradigm in the diagnosis and treatment of cancer.

The abstracts on Clarity's COBRA trial showcase the improved efficacy of ^{64}Cu-SAR-bisPSMA at detecting lesions compared to currently approved PSMA PET agents, and the potential for this product to become a best-in-class diagnostic. ^{64}Cu-SAR-bisPSMA was able to identify lesions prior to detection by the standard-of-care (SOC) PSMA PET products, which are known to have low sensitivity.

In a subset of participants in the COBRA study who underwent follow-up SOC PSMA PET, 70% of participants had a positive scan on same-day imaging and 90% on next-day imaging using ^{64}Cu-SAR-bisPSMA, compared to 60% of participants using SOC PSMA PET where only same-day imaging is possible. The number of lesions across all participants (average sum of lesions across all readers) identified by ^{64}Cu-SAR-bisPSMA was also higher (26.3 lesions on same-day imaging, 52.6 on next-day imaging) than that detected by SOC PET agents (20 lesions). Results indicate that ^{64}Cu-SAR-bisPSMA is able to identify lesions from 29 days to more than 6 months earlier than SOC PSMA agents. Across all participants in the study, histopathology confirmed the presence of prostate cancer in lesions identified by ^{64}Cu-SAR-bisPSMA in up to 78% of cases in which biopsies were performed, which was considerably higher compared to less sensitive methods (e.g. SOC imaging) used to verify the ^{64}Cu-SAR-bisPSMA PET findings. With regards to the biopsies, 100% of lesions which were located outside of the prostate bed were determined as positive, with only 2 participants showing negative results. These 2 participants had lesions located in the prostate bed and had undergone the complete removal of their prostate as part of their initial treatment. The prostate bed is an area notoriously difficult to biopsy following surgery due to anatomical changes and scarring of surrounding tissues as a result of the procedure, which may lead to negative results despite the presence of

cancer. Investigators stated that they would change their intended treatment plan in approximately half (48%) of their patients due to the findings of the ^{64}Cu-SAR-bisPSMA PET.

Clarity's Executive Chairperson, Dr Alan Taylor, commented, "Our lead product, SAR-bisPSMA, continues generating impressive results as we work with world-class experts to conduct clinical research at the highest standard, bringing us closer to improving the diagnostic paradigm for prostate cancer patients around the world. It is a huge testament to the quality and importance of our data that it continues to be accepted for presentation at some of the world's most prominent conferences.

"^{64}Cu-SAR-bisPSMA has shown an impeccable safety profile and impressive diagnostic performance to date compared to current SOC PSMA PET agents, which are known to have significant sensitivity limitations. Not only is our product more effective on same-day imaging due to its dual-targeting "bis" structure, but the unique property of next-day imaging, enabled by the longer half-life of copper-64 isotopes, also opens a myriad of opportunities for significantly improving the accuracy of cancer diagnosis and making more informed treatment decisions for men with prostate cancer.

"The results presented in the most recent COBRA abstracts highlight how ^{64}Cu-SAR-bisPSMA could change the scene of prostate cancer diagnostics. With 90% of next-day scans identifying prostate cancer, in comparison to only 60% on SOC PSMA PET scans, and identifying over 2.6 times the number of lesions with ^{64}Cu-SAR-bisPSMA over the approved diagnostics, ^{64}Cu-SAR-bisPSMA could be the game changer. The data provides physicians crucial information to make more informed decisions about treatment, and the high response from investigators in the COBRA trial who intended to change their treatment plan is an indication of how far reaching these changes could be. This opens the door for patients to potentially receive better treatment for their cancer based on these findings, improving their outcomes and quality of their lives.

"The data from the COBRA study, as well as from our earlier PROPELLER trial in the pre-prostatectomy setting, were used to support the design of our second registrational trial with ^{64}Cu-SAR-bisPSMA, AMPLIFY, in patients with biochemical recurrence (BCR) of prostate cancer, planned to commence in the coming months. This trial, in conjunction with the ongoing pivotal CLARIFY trial, which currently has over 20 sites actively recruiting in the U.S. and Australia, is intended to provide evidence to support the U.S. Food and Drug Administration (FDA) approval of ^{64}Cu-SAR-bisPSMA as a novel diagnostic imaging agent for newly diagnosed prostate cancer patients as well as those in BCR of their disease, bringing us closer to achieving our ultimate goal of improving treatment outcomes for people with cancer."

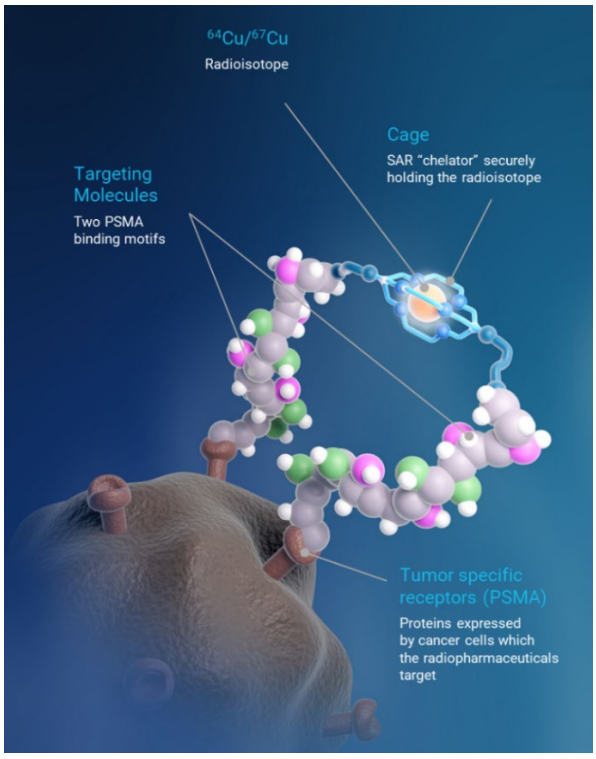
Title	Conference and Session details
COBRA: Assessment of the efficacy of ^{64}Cu-SAR-bisPSMA using histopathology as reference standard in patients with biochemical recurrence of prostate cancer following definitive therapy	**ASCO GU** **Date:** Thursday, February 13, 2025 **Time:** 11:25 AM – 12:45 PM PT; 5:45 PM – 6:45 PM PT **Session Title:** Trials in Progress Poster Session A: Prostate Cancer **Abstract #:** 44 **Poster Bd #:** A22
CLARIFY: Positron emission tomography using ^{64}Cu-SAR-bisPSMA in patients with high-risk prostate cancer prior	**ASCO GU** **Date:** Thursday, February 13, 2025

to radical prostatectomy – A phase 3 diagnostic performance study	**Time:** 11:25 AM – 12:45 PM PT; 5:45 PM – 6:45 PM PT **Session Title:** Trials in Progress Poster Session A: Prostate Cancer **Abstract #:** TPS429 **Poster Bd #:** M27
COBRA: Assessment of ^{64}Cu-SAR-bisPSMA and standard of care prostate-specific membrane antigen Positron Emission Tomography in patients with biochemical recurrence of prostate cancer following definitive therapy	**AUA** **Date:** Sunday, April 27, 2025 **Time:** 9:30 AM - 11:30 AM PT **Session Title**: MP13: Prostate Cancer: Staging **Room:** To be announced

Presentations will be available on Clarity's website after the conferences: claritypharmaceuticals.com/pipeline/scientific_presentations

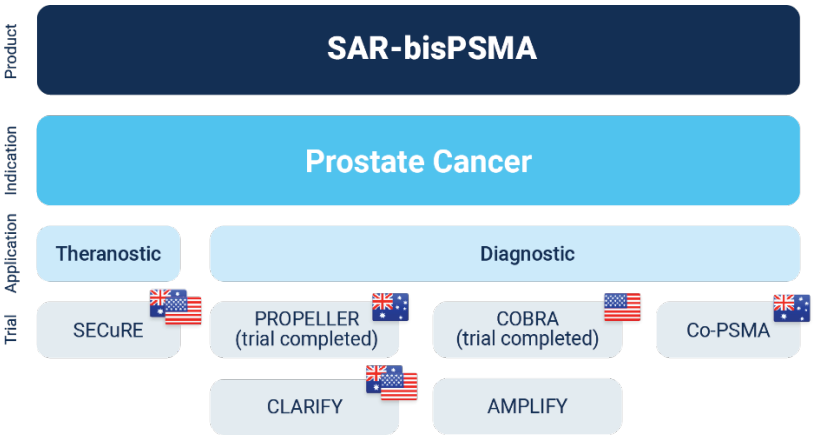
About SAR-bisPSMA

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.



^{64}Cu-SAR-bisPSMA is an unregistered product. The safety and efficacy of ^{64}Cu-SAR-bisPSMA has not been assessed by health authorities such as the U.S. FDA or the Therapeutic Goods Administration (TGA). There is no guarantee that this product will become commercially available. Among 82 patients who received ^{64}Cu-SAR-bisPSMA in PROPELLER and COBRA, 2 adverse reactions were reported in 2 participants (mild occasional metallic taste and moderate worsening of type II diabetes, both resolved)[1,2].

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[3]. Prostate cancer is the second-leading cause 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 U.S. and around 35,770 deaths from the disease[4].

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 in children and adults.

www.claritypharmaceuticals.com

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References

1. Lengyelova et al. ^{64}Cu-SAR-bisPSMA (PROPELLER) positron emission tomography (PET) imaging in patients with confirmed prostate cancer. ASCO, 2023.
2. 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.

3. Global Cancer Statistics 2022: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries, https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.21834
4. 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.