ASX ANNOUNCEMENT

22 December 2023

First patient dosed in Clarity's registrational Phase III prostate cancer trial with Cu-64 SAR-bisPSMA

Highlights

- First patient safely dosed in the pivotal Phase III ^{64}Cu-SAR-bisPSMA diagnostic trial, CLARIFY.
- The aim of the CLARIFY trial is to detect regional nodal metastases in participants with prostate cancer prior to radical prostatectomy.
- Final results from the CLARIFY trial are intended to provide sufficient evidence to support an application to the FDA for the approval of the ^{64}Cu-SAR-bisPSMA product in pre-prostatectomy patients.

Clarity Pharmaceuticals (ASX: CU6) ("Clarity"), 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 that the first patient has been dosed in its pivotal Phase III ^{64}Cu-SAR-bisPSMA diagnostic trial in prostate cancer, CLARIFY (NCT06056830)[1], at the Urology Cancer Center / XCancer Omaha, NE.

The aim of the CLARIFY study is to assess the diagnostic performance of ^{64}Cu-SAR-bisPSMA to detect regional nodal metastases in participants with high-risk prostate cancer prior to radical prostatectomy. The study will recruit 383 participants at multiple clinical sites across the United States and Australia.

Evaluation of the first patient is taking place over 2 imaging timepoints, day 1 (day of administration) and day 2 (approximately 24 hours post administration) and the patient will be followed up as per protocol. Subsequent patients will be evaluated in the same manner. As a pivotal trial, the final study results are intended to provide sufficient evidence to support an application to the FDA for approval of ^{64}Cu-SAR-bisPSMA as a new diagnostic imaging agent in prostate cancer in pre-prostatectomy patients.

Clarity's Executive Chairperson, Dr Alan Taylor, commented, "We are excited to have successfully dosed the first participant in the CLARIFY trial with our optimised SAR-bisPSMA agent. The trial is driven by the compelling findings from our PROPELLER trial (NCT04839367)[2,3] which highlighted the robust safety profile and superior performance of ^{64}Cu-SAR-bisPSMA compared to standard of care imaging (^{68}Ga-PSMA-11) with imaging on the day of administration, with two to three times the amount of product taken up in the lesions[2,3]. The longer half-life of copper-64 based diagnostics, in comparison to the currently used gallium-68 and fluorine-18 based products, also allows for delayed imaging. These unique features have the potential to enable detection of additional lesions compared to standard of care imaging and may address the significant shortfall in sensitivity of these agents. Additionally, the extended shelf-life of ^{64}Cu-SAR-bisPSMA of up to 48 hours, in contrast to the short shelf-life of currently available PSMA PET tracers, not only enhances scheduling flexibility for clinics, but also addresses a critical need for diagnostics in geographic areas with limited access to the current generation of radiopharmaceuticals.

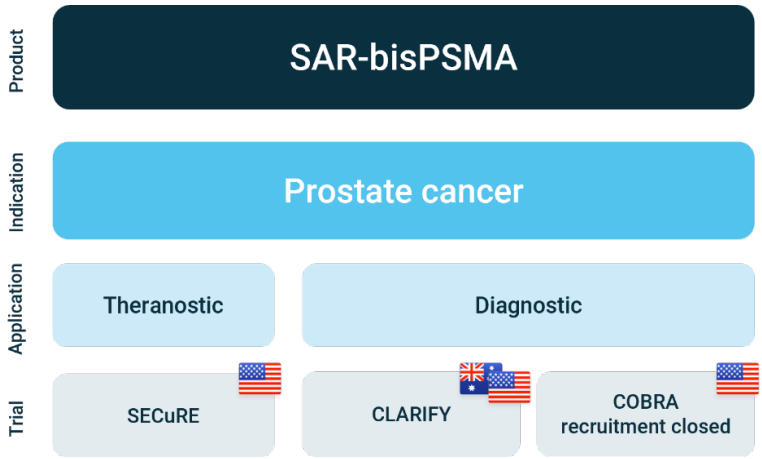
"Clarity is steadfast in addressing the high unmet need for diagnostics and therapies in the prostate cancer domain. Our optimism is rooted in the belief that our SAR-bisPSMA product can redefine diagnostic standards and improve patient outcomes. As we progress with the CLARIFY trial, we anticipate validating and building upon the positive data accumulated so far. Our vision is a future where enhanced diagnostic tools empower clinicians to make more informed decisions, ultimately shaping the optimal course of treatment for their patients."

"Although the current generation of PSMA-based radiopharmaceuticals is broadening the horizons of prostate cancer management and offering new treatment pathways for patients in need, we have seen in Clarity's PROPELLER trial that ^{64}Cu-SAR-bisPSMA has the potential of really changing this paradigm and outcomes for patients. We look forward to exploring and confirming these benefits in the CLARIFY trial."

About the CLARIFY trial

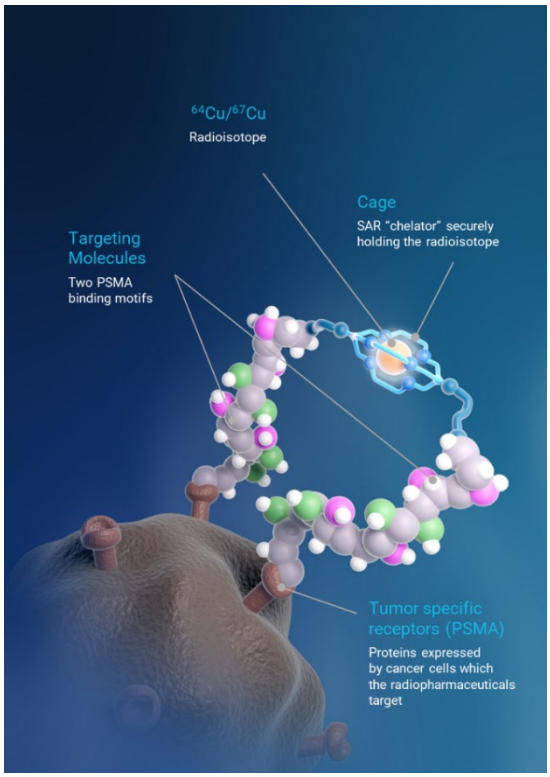
CLARIFY derives from "Positron Emission Tomography using ^{64}Cu-SAR-bisPSMA in participants with high-risk PC prior to radical prostatectomy: A prospective, single-arm, multi-centre, blinded-review, Phase III diagnostic performance study". It is a non-randomised, open-label clinical trial in 383 participants. The primary aim of the Phase III trial is to assess the diagnostic performance of ^{64}Cu-SAR-bisPSMA PET to detect regional nodal metastases. Furthermore, the safety, tolerability, and consistency of ^{64}Cu-SAR-bisPSMA will be assessed. All patients will receive a single administration of 200MBq ^{64}Cu-SAR-bisPSMA. Evaluation will take place over 2 imaging timepoints, Day 1 (day of administration) and Day 2 (approximately 24 hours post administration).

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 sarcophagene (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 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 and ^{67}Cu-SAR-bisPSMA are unregistered products. Individual results may not represent the overall safety and efficacy of the products. A clinical development program is currently underway to assess the efficacy and safety of these products. 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 worldwide[4]. The American Cancer Institute estimates in 2023 there will be 288,300 new cases of prostate cancer in the US and around 34,700 deaths from the disease[5].

About Clarity Pharmaceuticals

Clarity is a clinical stage radiopharmaceutical company focused on the treatment of serious disease. The Company is a leader in innovative radiopharmaceuticals, developing targeted copper theranostics based on its SAR Technology Platform for the treatment of cancer in children and adults.

www.claritypharmaceuticals.com

References

1. ClinicalTrials.gov Identifier: NCT06056830, https://clinicaltrials.gov/ct2/show/NCT06056830
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3. Lengyelova & Emmett et al. ^{64}Cu-SAR-bisPSMA (PROPELLER) positron emission tomography (PET) imaging in patients with confirmed prostate cancer. ASCO 2023. Poster available at: https://www.claritypharmaceuticals.com/pipeline/scientific_presentations/

4. 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
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This announcement has been authorised for release by the Executive Chairperson.