ASX ANNOUNCEMENT

29 May 2025

First patient imaged in Phase III AMPLIFY trial with ^{64}Cu-SAR-bisPSMA PET/CT

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 it has imaged the first patient in its registrational Phase III ^{64}Cu-SAR-bisPSMA diagnostic trial in participants with biochemical recurrence (BCR) of prostate cancer, AMPLIFY (NCT06970847)[1], at XCancer in Omaha, Nebraska (NE).

Dr Luke Nordquist, Urologic Medical Oncologist, CEO, XCancer, commented, "We are thrilled to recruit the first participant in the AMPLIFY trial and to image them just over a week after study initiation. ^{64}Cu-SAR-bisPSMA could become a best-in-class diagnostic prostate-specific membrane antigen (PSMA) agent, and we are honoured to be part of this registrational trial that intends to gather sufficient data for a New Drug Application (NDA) and a potential subsequent commercialisation of this next-generation product.

"We have already observed the potential benefits of ^{64}Cu-SAR-bisPSMA based on data from earlier phase trials such as Clarity's PROPELLER and COBRA studies and look forward to participating in the AMPLIFY trial, providing this optimised product to our patients in need of novel diagnostic solutions. The COBRA trial[2] that laid foundation for AMPLIFY in patients with BCR of prostate cancer showed that more lesions and more patients with a positive scan were identified on ^{64}Cu-SAR-bisPSMA positron emission tomography (PET) compared to conventional scans and on next-day vs. same-day imaging. ^{64}Cu-SAR-bisPSMA also allowed for the identification of lesions in the 2-mm range and was able to detect lesions at least 6 months earlier than the current standard-of-care (SOC) PSMA PET agents. The team at XCancer looks forward to further building on this evidence in the AMPLIFY trial as we progress towards our mutual goal of improving treatment outcomes for patients with cancer."

Clarity's Executive Chairperson, Dr Alan Taylor, commented, "We are excited to have imaged the first patient in the AMPLIFY trial and look forward to further progressing recruitment and opening clinical sites across the United States (US) and Australia, providing access to ^{64}Cu-SAR-bisPSMA in both countries as part of this trial. We have built a robust supply of copper-64 with a wide network of product manufacturers in preparation for our two Phase III trials, AMPLIFY in BCR and CLARIFY[3] in pre-prostatectomy, and potential commercialisation. As such, we are ideally positioned to build on the clinical advantages of ^{64}Cu-SAR-bisPSMA based on its higher lesion uptake and contrast, increased lesion detection rate compared to SOC imaging and flexible imaging schedule, enabled by its dual targeting (bisPSMA), proprietary chelator technology (sarcophagine, SAR) and copper-64 properties. We are also prepared to fully leverage the logistical and supply chain advantages associated with the optimal half-life of this isotope, in comparison to short-lived gallium-68 and fluorine-18, which allows ^{64}Cu-SAR-bisPSMA to be made centrally in one location and shipped on-demand to any treatment facility in the country. This model enables better access and geographic distribution, meaning men with cancer could get an accurate and early diagnosis whether their location is a major city or regional area, as long as there is a PET camera on site.

"With prostate cancer prevalence increasing year after year, we look forward to overcoming limitations of the current-generation PSMA PET diagnostics, such as sensitivity and accessibility, making earlier and more accurate detection of recurrent disease a potential reality and bringing our optimised diagnostic to more men with this insidious disease around the world."

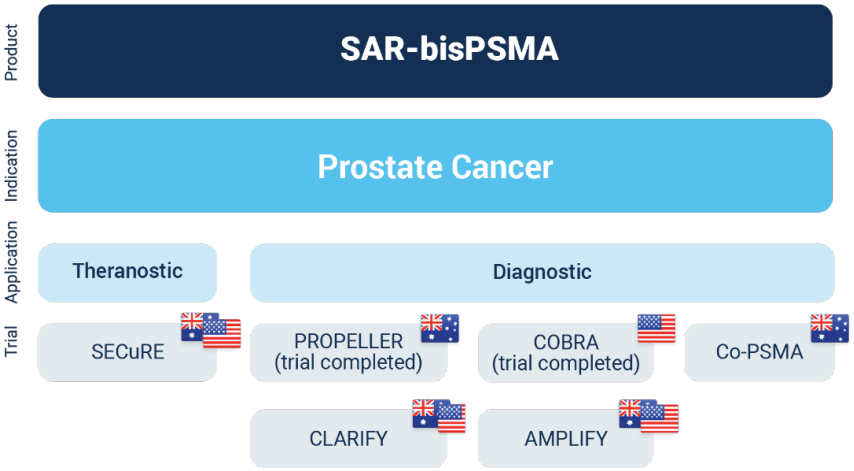
About the AMPLIFY trial

AMPLIFY's official title is "^{64}Cu-SAR-bisPSMA Positron Emission Tomography: A Phase 3 Study of Participants with Biochemical Recurrence of Prostate Cancer" (NCT06970847)[1]. It is a non-randomised, single-arm, open-label, multi-centre, diagnostic clinical trial of ^{64}Cu-SAR-bisPSMA PET in participants with rising or detectable prostate-specific antigen (PSA) after initial definitive treatment.

The aim of this trial is to investigate the ability of ^{64}Cu-SAR-bisPSMA PET/computed tomography (CT) to detect recurrence of prostate cancer, with evaluation across 2 imaging timepoints, Day 1 (day of administration, same-day imaging) and Day 2 (approximately 24 hours post administration, next-day imaging).

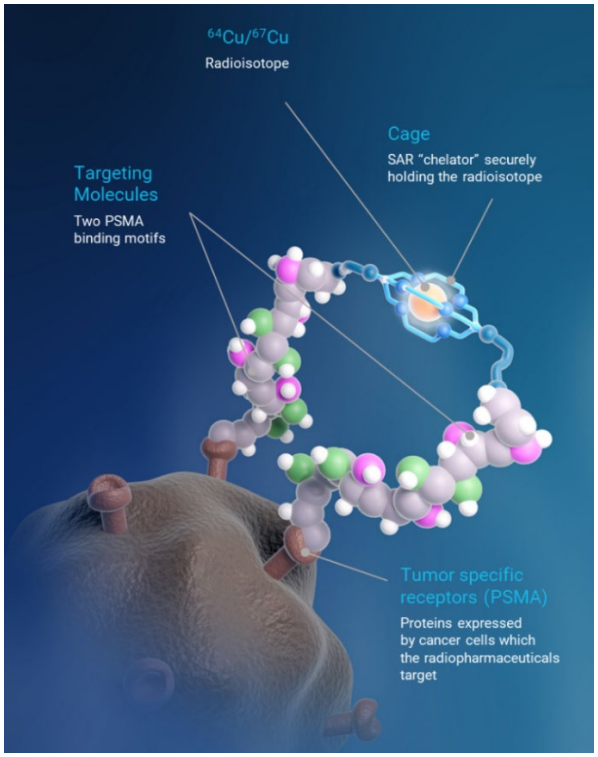
The study will enroll approximately 220 participants at multiple clinical sites across the US and Australia. As a pivotal trial, the final study results are intended to provide sufficient evidence to support an application to the US Food and Drug Administration (FDA) for approval of ^{64}Cu-SAR-bisPSMA as a new diagnostic imaging agent in BCR of prostate cancer.

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.



Disclaimer

^{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 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[4]. Prostate cancer is the second-leading causes 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 US and around 35,770 deaths from the disease[5].

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

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References

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