ASX ANNOUNCEMENT

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Registrational Phase III AMPLIFY trial in biochemical recurrence of prostate cancer commences

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 commenced its second registrational Phase III ^{64}Cu-SAR-bisPSMA diagnostic trial in prostate cancer, AMPLIFY (NCT06970847)[1], with the initiation of the first clinical site at XCancer in Omaha, NE.

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

The aim of this Phase III trial is to investigate the ability of ^{64}Cu-SAR-bisPSMA PET/computed tomography (CT) to detect recurrence of prostate cancer. Evaluation will be 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 United States (US) and Australia, and the first participant is expected to be imaged in the coming weeks. 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 biochemical recurrence (BCR) of prostate cancer.

Clarity's Executive Chairperson, Dr Alan Taylor, commented, "We are very excited to commence our second registrational Phase III trial with the optimised SAR-bisPSMA agent in patients that are experiencing the return of their disease following treatment of the primary cancer.

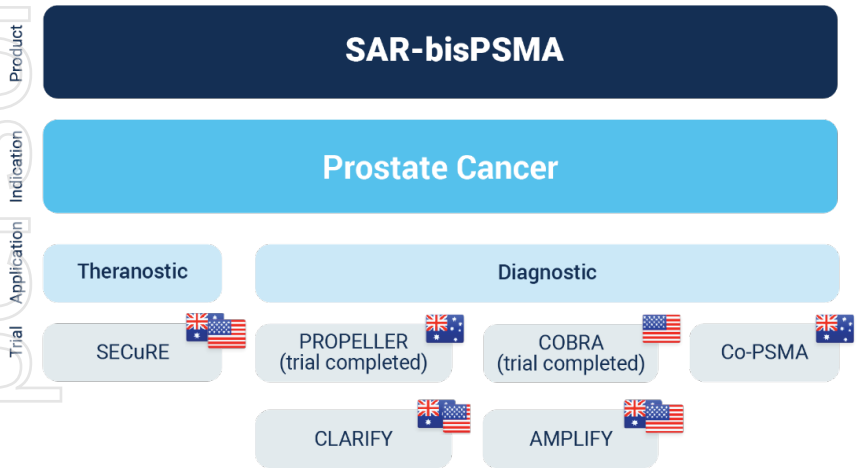
"The recent devastating news that former US President, Joe Biden, has been diagnosed with aggressive prostate cancer that has metastasised to the bone is yet another reminder that no man is safe from this insidious disease, and he joins over 3.3 million men in the US who live with prostate cancer today[2]. Australia is also not immune. A recent public announcement revealed that MP Barnaby Joyce has recently been diagnosed with prostate cancer, and he joins over 250,000 Australian men who are living with prostate cancer today[3]. These large numbers highlight the need for more timely and accurate diagnosis to safely and effectively treat the cancer with suitable therapies."

The AMPLIFY trial is based on favourable preclinical and clinical data generated to date, including the Phase I/II COBRA trial in patients with BCR of prostate cancer and the Phase I PROPELLER trial in patients with confirmed prostate cancer pre-prostatectomy[4,5]. These earlier studies demonstrated an excellent safety profile and exciting efficacy results, especially in comparison to current standard of care imaging. PROPELLER showed improved diagnostic performance of ^{64}Cu-SAR-bisPSMA compared to ^{68}Ga-PSMA-11 on same-day imaging, including higher number of lesions identified and 2-3 times higher uptake and tumour-to-background ratio, favouring ^{64}Cu-SAR-bisPSMA. The COBRA trial showed that more lesions and more patients with a positive scan were identified on ^{64}Cu-SAR-bisPSMA 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. The most recent findings from the COBRA trial demonstrated that ^{64}Cu-SAR-bisPSMA was able to detect lesions from 29 days to more than 6 months earlier than standard-of-care (SOC) prostate-specific membrane antigen (PSMA) PET agents.

"These compelling findings, along with preliminary theranostic SECuRE trial data[6], laid the foundation for the receipt of three Fast Track Designations (FTD) for SAR-bisPSMA from the US FDA within six months[7-9], highlighting how impressive our science and clinical development are, the significance of the data so far and the high unmet need for better therapies and diagnostics in prostate cancer. We believe ^{64}Cu-SAR-bisPSMA could become a best-in-class product and look forward to progressing its clinical development through several trials in prostate cancer: AMPLIFY in BCR, our first Phase III CLARIFY study in pre-prostatectomy patients, the investigator-initiated trial led by Prof Louise Emmett, Co-PSMA (head-to-head study comparing the diagnostic performance of ^{64}Cu-SAR-bisPSMA vs. SOC ^{68}Ga-PSMA-11 in BCR), and the theranostic SECuRE study in metastatic castration-resistant prostate cancer (mCRPC). The FTDs will enable us to accelerate the development of this comprehensive program to be used in patients with prostate cancer throughout the management of their cancer, from initial to late-stage disease, with an opportunity to completely change the entire treatment landscape for the large prostate cancer market.

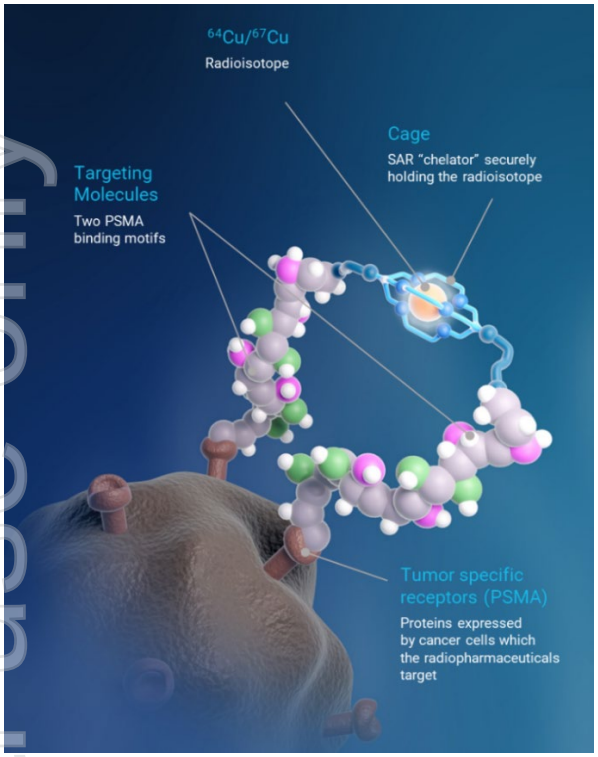
"We have received a lot of interest in the AMPLIFY trial and look forward to seeing this study progress in such an important patient population. Knowing whether or not their prostate cancer has returned following initial treatment and where the cancer lesions are located are essential for the appropriate treatment of BCR patients. Identifying lesions as early as possible can arm clinicians with important information to help determine the right treatment regimen and ensure positive long-term treatment outcomes. We would like to thank all clinicians and patients who participate in our clinical trials and who trust us in delivering on our promise of developing best-in-class products. Our team and collaborators look forward to bringing this next-generation PSMA diagnostic to prostate cancer patients around the world," **said Dr Taylor**.

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[10]. 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[2].

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