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Recruitment opens for Phase II trial in prostate cancer with Cu-64 SAR-Bombesin in the US

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 US-based diagnostic ^{64}Cu SAR-Bombesin trial (SABRE NCT05407311)[1] for patients with PSMA-negative prostate cancer is open for recruitment.

SABRE (Copper-64 SAR-BisPSMA in Biochemical Recurrence of prostate cancer) is a Phase II Positron Emission Tomography (PET) imaging trial of participants with PSMA-negative biochemical recurrence (BCR) of prostate cancer following definitive therapy. It is a multi-centre, single arm, non-randomised, open-label trial of ^{64}Cu-labelled SAR-Bombesin in 50 participants. The primary objectives of the trial are to investigate safety and tolerability of the product as well as its ability to correctly detect recurrence of prostate cancer.

Dr Andrei Iagaru, Lead Principal Investigator in the SABRE trial, commented, "We are very excited to initiate patient accrual for the SABRE trial which will explore and validate the clinical benefits associated with the novel SAR-Bombesin agent. We have been investigating Bombesin for many years and believe it is an agent with high diagnostic and therapeutic potential. We hope this trial will inform us on the role of SAR-Bombesin in diagnosing disease in PSMA-negative prostate cancer patients by imaging patients on day of injection and at ~24 hours after injection, with the delayed imaging being a novel feature enabled by ^{64}Cu. In addition to investigating the clinical benefits of the product, we also look forward to leveraging centralised manufacture and on-demand delivery advantages of copper-based products. These features have potential to facilitate universal access to SAR-Bombesin and enhance accessibility to treatment facilities throughout the US.

"We look forward to expanding the trial sites and generating data for this next-generation product which could ensure both ease of access and improved treatment outcomes for BCR prostate cancer patients," **said Dr Iagaru.**

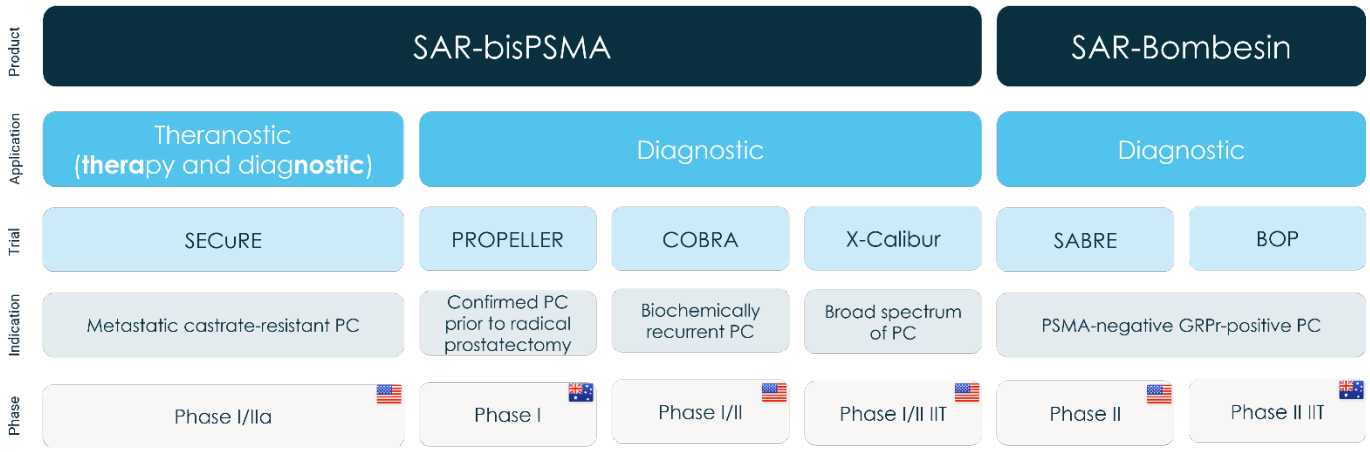
The SABRE trial was developed in response to strong demand from clinicians with prostate cancer patients whose cancer was not visible with currently approved PSMA diagnostic agents or conventional imaging (such as CT or MRI). It builds on the data generated in PSMA-negative prostate cancer patients at St Vincent's Hospital imaged under the Therapeutic Goods Administration (TGA) Special Access Scheme (SAS).[2] This data has demonstrated diagnostic imaging potential in PSMA-negative prostate cancer and highlighted potential utility of the product as a theranostic agent. SABRE also builds on a pilot diagnostic trial of SAR-Bombesin in breast cancer patients, the C-BOBCAT trial, which was recently presented at the prestigious American Society of Clinical Oncology (ASCO) 2022 Annual Meeting.[3]

Clarity's Executive Chairman, Dr Alan Taylor, commented, "We are excited to commence recruitment into the SABRE trial, having only received our Study May Proceed letter from the US Food and Drug Administration (FDA) in June. SABRE reinforces our commitment to running Clarity's clinical trials for first approvals in the US under clinical protocols which have been reviewed by the US FDA. Subject to the outcomes of this Phase II trial, we will look to progress this diagnostic product into Phase III trials in the US as soon as possible.

"Given the promising data to date, indicating potential diagnostic and therapeutic benefits of SAR-Bombesin, we are committed to continuing generating data on the product with the SABRE trial following in quick succession from the BOP investigator-initiated trial in PSMA-negative prostate cancer participants that commenced at St Vincent's Hospital in Sydney earlier this month. In parallel, we are also preparing a submission to the US FDA for an Investigational New Drug (IND) application for a therapeutic clinical trial with the product later this year.

"We look forward to recruiting and imaging participants in the SABRE trial and gathering further evidence of clinical, environmental and logistical benefits of SAR-Bombesin, hoping that it will provide a large patient population with accurate and precise detection and treatment of PSMA-negative prostate cancer," **said Dr Taylor**.

Clarity's Prostate Cancer clinical trial program overview



About SAR-Bombesin

SAR-Bombesin is a highly targeted pan-cancer radiopharmaceutical with broad cancer application. It targets the gastrin-releasing peptide receptor (GRPr) present on cells of a range of cancers, including but not limited to prostate, breast and ovarian cancers. GRPr is found in approximately 75-100% of prostate cancers, including prostate cancers that don't express PSMA (PSMA-negative)[4-8]. The product utilises 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-Bombesin 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).

About Prostate Cancer

Prostate cancer is the second most common cancer diagnosed in men globally and the fifth leading cause of cancer death worldwide[9]. The National Cancer Institute estimates in 2022 there will be 268,490 new cases of prostate cancer in the US and around 34,500 deaths from the disease[10].

Approximately 20% of prostate cancers with BCR are PSMA-PET negative[11-14]. These patients are therefore unlikely to respond to therapeutic PSMA-targeted products and currently have few treatment options available to them. Given the prostate cancer indication is one of the largest in oncology, there is a significant unmet medical need in this segment.

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

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