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Recruitment target achieved for Phase II SAR-Bombesin prostate cancer trial

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 50 patients have now been imaged with ^{64}Cu-SAR-Bombesin in its United States-based diagnostic trial, SABRE (NCT05407311)[1], for participants with PSMA-negative prostate cancer.

SABRE, which derives from "Copper-64 **SA**R-BisPSMA in **B**iochemical **Re**currence 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. The primary objectives of the trial are to investigate the safety and tolerability of the product as well as its ability to correctly detect recurrence of prostate cancer.

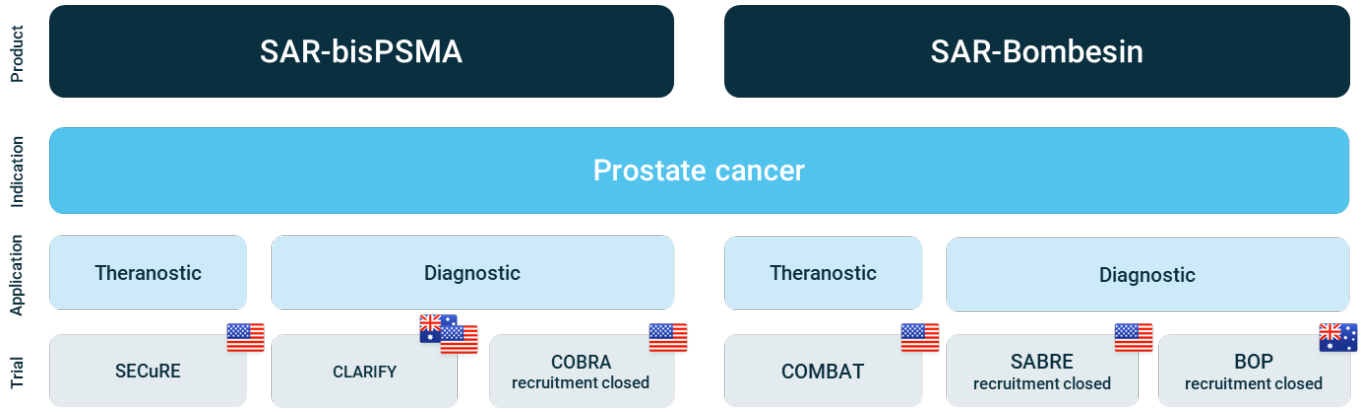
Andrei Iagaru, MD, the Lead Principal Investigator for the trial, commented, "We are very excited to have successfully imaged 50 participants in the SABRE trial which further explores the clinical benefits of the innovative SAR-Bombesin product. Preclinical and clinical findings thus far indicate that SAR-Bombesin holds significant potential for improving the diagnosis and treatment of prostate cancer, giving hope to clinicians and patients who have no other suitable diagnostic options available. Being able to now visualise the gastrin-releasing peptide receptor (GRPr) expressing lesions with SAR-Bombesin has the potential to change the entire treatment paradigm for patients. With more tools to detect prostate cancer that may not be visible with other imaging agents, we may be able to better diagnose and offer more effective treatment for their disease.

"Unique to Clarity's SAR Technology is the ability to image patients at later timepoints due to the optimal half-life of ^{64}Cu. As such, ^{64}Cu-SAR-Bombesin enables imaging not only on the day of product administration, but also at later timepoints, which may add utility to the diagnosis of cancerous lesions. We look forward to analysing data from the SABRE trial in hopes of continuing to validate the benefits associated with this agent and better managing the patients that have few options at present in the face of a devastating diagnosis."

Clarity's Executive Chairman, Dr Alan Taylor, commented, "We are pleased to have reached our recruitment target in our Phase II SABRE trial with the ^{64}Cu-SAR-Bombesin imaging product. SAR-Bombesin has already resulted in improvements to the management of prostate cancer for patients with PSMA-negative or low PSMA expressing lesions through our clinical program. We believe this product has immense potential, both as a theranostic and as a stand-alone diagnostic, as it targets GRPr, which is present in a number of cancers, potentially broadening its use beyond PSMA-negative prostate cancer.

"The successful C-BOBCAT and BOP investigator-initiated trials have already showed the utility of SAR-Bombesin and its potential to identify disease in some patient subgroups where conventional diagnostic imaging has failed. We look forward to reporting further data relating to the potential advantages of SAR-Bombesin and, subject to these results, moving this product into a registrational Phase III trial."

Clarity's active 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 up to 100% of prostate cancers, including prostate cancers that don't express PSMA (PSMA-negative)[2-6]. 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.

^{64}Cu-SAR-Bombesin and ^{67}Cu-SAR-Bombesin are unregistered products. Individual results may not represent the overall safety and efficacy of the products. The data outlined in this announcement has not been assessed by health authorities such as the US Food and Drug Administration (FDA). 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[7]. 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[8].

Approximately 20% of prostate cancers with BCR are PSMA-PET negative[9-12]. 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.