ASX ANNOUNCEMENT

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IND approval from the US FDA for Phase II SAR-Bombesin imaging trial in prostate cancer

Highlights

- IND approval received for SAR-Bombesin product, enabling a Phase II "SABRE" imaging trial to detect prostate cancer in up to 50 PSMA-negative participants in the US
- Approximately 20% of prostate cancer patients with biochemical recurrence (BCR) are PSMA-PET negative and therefore unsuitable for the currently approved PSMA targeting agents, presenting an opportunity to target these cancers with Clarity's SAR-Bombesin product

Clarity Pharmaceuticals (ASX: CU6) ("Clarity"), a clinical-stage radiopharmaceutical company developing next-generation products to address growing medical needs in oncology, announces the approval of its Investigational New Drug (IND) application by the United States Food and Drug Administration (US FDA) to evaluate its SAR-Bombesin product as an imaging agent in prostate cancer patients that are Prostate-Specific Membrane Antigen (PSMA)-negative.

Clarity's Executive Chairman, Dr Alan Taylor, commented, "Receiving clearance from the FDA on the imaging trial with SAR-Bombesin is yet another significant milestone for Clarity. It shows our ability to develop cutting-edge theranostics from the lab, through preclinical studies and into clinical trials, with SAR-Bombesin being Clarity's fourth IND across five products which are clear for investigation in the US."

This IND gives Clarity clearance to proceed with a US-based Phase II ^{64}Cu SAR-Bombesin Positron Emission Tomography (PET) imaging trial in participants with PSMA-negative BCR of prostate cancer following definitive therapy (such as surgery or radiation).

SABRE, which derives from "Copper-64 SAR-Bombesin in Biochemical RECurrence of Prostate Cancer trial", is a multi-center, single arm, non-randomised, open-label trial in up to 50 PSMA-negative patients with known or suspected prostate cancer. The primary objectives of the trial are to investigate the safety and tolerability of ^{64}Cu SAR-Bombesin, as well as its ability to correctly detect the recurrence of prostate cancer.

The SABRE trial builds upon the promising clinical data from the pilot trial assessment of ^{64}Cu SAR-Bombesin in breast cancer led by Prof Louise Emmett of St Vincent's Hospital Sydney. The data from this trial was recently presented at the prestigious American Society of Clinical Oncology (ASCO) 2022 Annual Meeting. The SABRE trial was developed in response to the strong demand for this product from clinicians with prostate cancer patients whose cancer was not visible with currently approved PSMA diagnostic agents or conventional imaging (such as CT and/or MRI). Their patients were successfully imaged with ^{64}Cu SAR-Bombesin under a Special Access Scheme.

Approximately 20% of prostate cancers with BCR are PSMA-PET negative[1-4]. 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. The SAR-Bombesin product targets the Gastrin Releasing Peptide receptor (GRPr) found on prostate and many other cancers. As such, the product could offer valuable imaging and therapeutic options for not only PSMA negative patients, but also the large number of patients that have the target receptor on their cancers.

"We look forward to further progressing the development of SAR-Bombesin and hope it will provide a new and effective diagnostic option for prostate cancer patients. Building on the promising clinical and preclinical data acquired to date, we are also planning an IND submission for a theranostic trial in prostate cancer participants, using ^{67}Cu SAR-Bombesin therapy paired with the imaging agent, ^{64}Cu SAR-Bombesin. Combined with the clinical, environmental and logistical benefits enabled by the copper isotope pairing, SAR-Bombesin has potential to provide this large patient population with accurate and precise detection and treatment of prostate cancer. We anticipate the SABRE trial to commence shortly and the theranostic trial to commence in 2023," **Dr Taylor added.**

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

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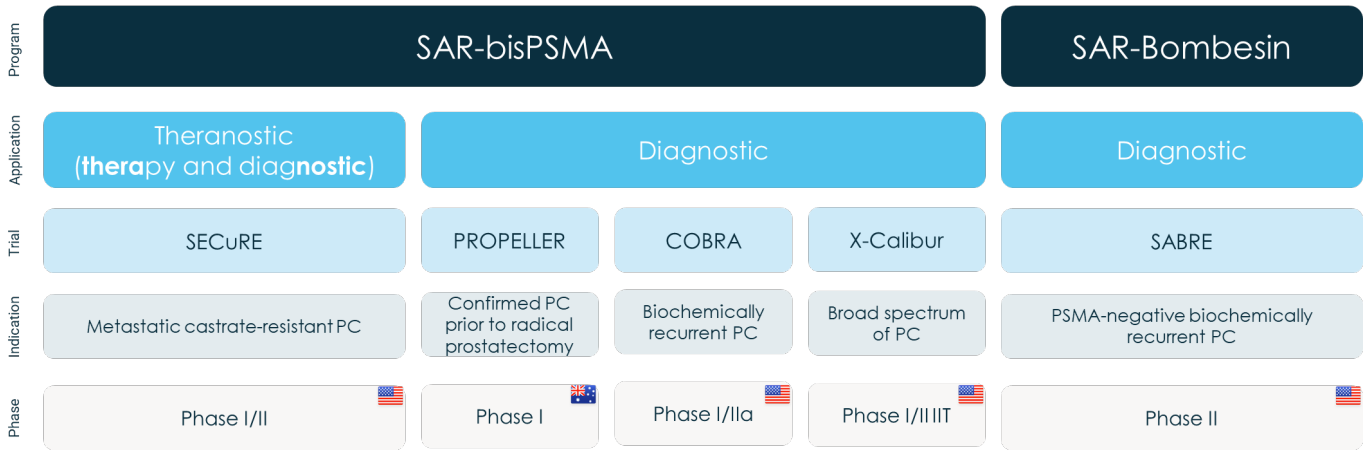
About Clarity Pharmaceuticals

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

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)[5-9]. 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[10]. 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[11].

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