

ASX ANNOUNCEMENT

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Imaging trial with SAR-Bombesin in prostate cancer opens for recruitment in Australia

Highlights

- Diagnostic investigator-initiated trial (IIT) with one of Clarity' core products, SAR-Bombesin, commenced at St Vincent's Hospital Sydney, led by Prof Louise Emmett.
- The Phase II IIT 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) as well as from the pilot diagnostic IIT of SAR-Bombesin in breast cancer patients (C-BOBCAT)
- A significant proportion of prostate cancer patients express the target for SAR-Bombesin, and 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 with a mission to develop next-generation products that improve treatment outcomes for children and adults with cancer, is pleased to announce that the diagnostic ⁶⁴Cu SAR-Bombesin trial (BOP) for patients with prostate cancer is open for recruitment in Australia.

BOP (Copper-64 SAR **B**ombesin in **P**SMa negative Prostate Cancer (BOP) is a Phase II investigator-initiated trial (IIT) in up to 30 patients led by Prof Louise Emmett at St Vincent's Hospital Sydney. The BOP trial will be assessing the safety of ⁶⁴Cu-SAR-Bombesin as well as looking at the diagnostic potential for men with negative prostate specific membrane antigen (PSMA) positron emission tomography (PET) or low PSMA expression disease in patients with suspected biochemical recurrence (BCR) of their prostate cancer and patients with metastatic castrate resistant prostate cancer (mCRPC) who are not eligible for PSMA therapy. The trial will be imaging with ⁶⁴Cu SAR-Bombesin on the day of administration as well as at later timepoints.

Approximately 20% of prostate cancers with BCR are PSMA-PET negative¹⁻⁴. 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 up to 100% of prostate cancers⁵⁻⁹ as well as 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.

BOP builds on the data generated in PSMA-negative prostate cancer patients at St Vincent's Hospital imaged under TGA SAS as well as from pilot diagnostic IIT 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.

Prof Louise Emmett (St Vincent's Hospital Sydney), Principal Investigator in the BOP trial, commented, "The data we acquired to date for SAR-Bombesin through SAS, published as a case study¹⁰, has demonstrated diagnostic imaging potential in PSMA-negative prostate cancer and highlighted potential utility of the product as a theranostic agent. At St Vincent's Hospital we imaged four men with ⁶⁴Cu SAR-Bombesin under SAS. They had rising PSA levels but no detectable disease using currently available imaging techniques. SAR-Bombesin was able to detect disease in these patients which successfully led to changes in management of the patient and their disease.







"We are excited by the prospect of making SAR-Bombesin available to a larger pool of patients under clinical trial conditions so that we can carefully analyse the role of this product in the better management of patients. In addition, the central manufacture of these products enables more flexibility in administering the product and has the potential to improve scheduling due to a longer shelf-life in comparison to commonly used diagnostic isotopes such as ⁶⁸Ga and ¹⁸F.

"I am very pleased to be working with Clarity on the Targeted Copper Theranostic (TCT) platform of products. The BOP trial investigating ⁶⁴Cu SAR-Bombesin is our third trial using Clarity's TCTs range of products," **said Prof Emmett.**

Clarity's Executive Chairman, Dr Alan Taylor, commented, "The early data we are generating on our SAR-Bombesin product is already changing the lives of patients with cancer. We are looking forward to progressing the development of this product in Australia and the US for diagnostic and therapeutic applications, hoping that it will provide new options for cancer patients who have few treatment options available to them at present. We believe that SAR-Bombesin has potential to provide large patient populations with accurate and precise detection and treatment of cancers that express the target and deliver clinical, environmental and logistical benefits enabled by the copper isotope pairing."

"BOP is yet another part of our collaboration with St Vincent's Hospital and Prof Louise Emmett and we look forward to continuing our work on the development of TCTs with the mutual goal of improving treatment outcomes for children and adults with cancer" **said Dr Taylor.**

Clarity's Prostate Cancer clinical trial program overview

Product	SAR-bisPSMA				SAR-Bombesin	
Application	Theranostic (therapy and diagnostic)		Diagnostic		Diagnostic	
Trial	SECURE	PROPELLER	COBRA	X-Calibur	SABRE	BOP
Indication	Metastatic castrate-resistant PC		Confirmed PC prior to radical prostatectomy	Biochemically recurrent PC	Broad spectrum of PC	PSMA-negative GRPr-positive PC
Phase	Phase I/IIa 	Phase I 	Phase I/II 	Phase I/II IIT 	Phase II 	Phase II IIT 

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 ⁶⁴Cu) for imaging and copper-67 (Cu-67 or ⁶⁷Cu) 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 worldwide¹¹. 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 disease¹².

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.