

ASX ANNOUNCEMENT

14 September 2022

First participants imaged in SAR-Bombesin prostate cancer trial in Australia

Highlights

- First participants were recruited and imaged in the diagnostic investigator-initiated trial (IIT) led by Prof Louise Emmett at St Vincent's Hospital Sydney with one of Clarity's core products, SAR-Bombesin
- The Phase II IIT builds on the data generated in PSMA-negative prostate cancer patients imaged at St Vincent's Hospital under the Therapeutic Goods Administration (TGA) Special Access Scheme (SAS) as well as from the pilot diagnostic IIT investigating 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. These patients are 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 it has successfully imaged its first participants in the diagnostic ⁶⁴Cu SAR-Bombesin trial (BOP) for patients with PSMA-negative prostate cancer in Australia.

BOP (Copper-64 SAR **B**ombesin in **P**rostate Specific Membrane Antigen (PSMA) negative Prostate Cancer) 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 is assessing the safety of ⁶⁴Cu-SAR-Bombesin as well as looking at the diagnostic potential across two different groups of men:

1. Participants with suspected biochemical recurrence (BCR) of their prostate cancer who have negative PSMA positron emission tomography (PET) imaging scans or low PSMA expression disease.
2. Participants with metastatic castrate resistant prostate cancer (mCRPC) who are not eligible for PSMA therapy.

The trial is imaging with ⁶⁴Cu SAR-Bombesin on the day of administration as well as at later timepoints.







Prof Louise Emmett (St Vincent's Hospital Sydney), Principal Investigator in the BOP trial, commented, "We are very pleased to have recruited and imaged the first participants in this study. The SAR-Bombesin product is a promising target for a large patient population with a high unmet need and few treatments available to them. We are excited to now make the product available to a larger pool of patients under clinical trial conditions".

"SAR-Bombesin has already shown very promising data to date through a SAS case study¹, demonstrating diagnostic imaging potential in PSMA-negative prostate cancer and highlighting potential utility of the product as a theranostic agent. We are now looking forward to further investigating the role of SAR-Bombesin in the better management of patients," **said Prof Emmett.**

Clarity's Executive Chairman, Dr Alan Taylor, commented, "The commencement of this trial is yet another step forward in our collaboration with Prof Emmett and St Vincent Hospital Sydney as the BOP IIT is now our third clinical trial conducted in partnership. We are pleased that this collaboration has already resulted in changes in the management of the disease for patients in our own city of Sydney, as we head towards our ultimate goal of improving treatment outcomes for children and adults with cancer around the world."

"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," **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)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 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 worldwide⁷. 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 disease⁸.

Approximately 20% of prostate cancers with BCR are PSMA-PET negative⁹⁻¹². 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. The SAR-Bombesin 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.

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.