

## ASX MEDIA RELEASE

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## 50% recruitment milestone reached for Phase II BOP 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 the Phase II diagnostic <sup>64</sup>Cu SAR-Bombesin trial (BOP) for patients with prostate cancer has reached the fifty percent recruitment milestone, with 15 out of 30 participants enrolled and imaged.

**Prof Louise Emmett (St Vincent's Hospital Sydney), Principal Investigator in the BOP trial, commented,** "We are very excited with the fast pace of recruitment into the BOP trial. We dosed the first patient in mid-September and have reached a 50% recruitment milestone less than 2 months later. The data we are generating will help to explore and validate the clinical benefits of the SAR-Bombesin product. We look forward to recruiting the remaining 15 patients in the trial and analysing the study results.

"We believe SAR-Bombesin will play a role in the identification of disease that is not observed with conventional imaging or PSMA-PET. This could ultimately lead to more effective treatments for this large patient population where unfortunately, very few treatment options are available at present."







**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 <sup>64</sup>Cu-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.

**Clarity's Executive Chairman, Dr Alan Taylor, commented,** "The rapid progress of the BOP IIT, led by Prof Emmett and her team at St Vincent's Hospital, is testament to the hard work and dedication to our mutual goal of improving treatment outcomes for people with cancer. We are motivated and driven by the progress on our collaboration as it has already resulted in improvements to the management of the disease for patients with PSMA-negative prostate cancer.

"The BOP trial builds on the data Prof Emmett's team generated in PSMA-negative prostate cancer patients imaged under the Therapeutic Goods Administration Special Access Scheme, as well as from the pilot diagnostic trial investigating SAR-Bombesin in breast cancer patients. The data indicates potential utility of the product as a theranostic agent. As such, Clarity plans to progress the therapy under an Investigational New Drug application with the US Food and Drug Administration for the commencement of a theranostic trial with SAR-Bombesin in the US. We believe SAR-Bombesin has the potential to provide large patient populations with accurate and precise detection and treatment of cancers."

## 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)<sup>1-5</sup>. 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 <sup>64</sup>Cu) for imaging and copper-67 (Cu-67 or <sup>67</sup>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<sup>6</sup>. 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<sup>7</sup>.

Approximately 20% of prostate cancers with BCR are PSMA-PET negative<sup>8-11</sup>. 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](http://www.claritypharmaceuticals.com)

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