**ASX MEDIA RELEASE**

7 June 2023

# Recruitment complete for Phase II prostate cancer trial

**Clarity Pharmaceuticals** (ASX: CU6) ("Clarity", "the Company"), 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 completion of recruitment for the Phase II investigator initiated diagnostic trial, BOP (NCT05613842)[1], evaluating its $^{64}$Cu-SAR-Bombesin product in 30 participants with prostate cancer.

**BOP** (Copper-64 SAR Bombesin in Prostate Specific Membrane Antigen (PSMA) negative Prostate Cancer) is a Phase II investigator-initiated trial (IIT) in 30 patients led by Prof Louise Emmett at St Vincent's Hospital, Sydney. The BOP trial is assessing the safety of $^{64}$Cu-SAR-Bombesin as well as looking at the diagnostic potential across two different groups of men:

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

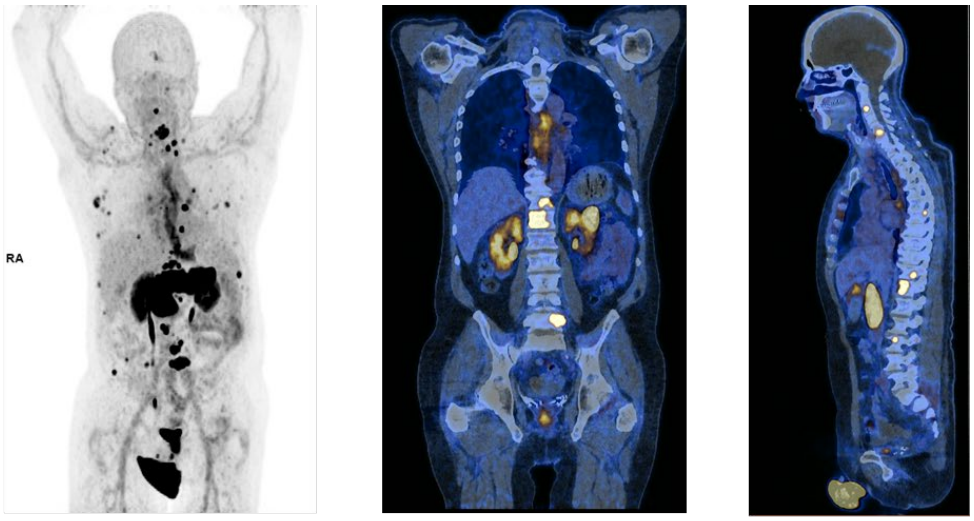
**Prof Louise Emmett (St Vincent's Hospital Sydney), Principal Investigator in the BOP trial, commented,** "We are very excited with the preliminary results we have generated in the BOP trial to date and believe $^{64}$Cu SAR-Bombesin has the potential to play an important role in the diagnosis of prostate cancer lesions that cannot be detected with conventional imaging or PSMA-PET agents, such as tumours that are PSMA-negative or have low PSMA expression. The ability to detect and visualise the cancer correctly holds promise of better treatment outcomes for these patients through more appropriate therapeutic regimens. We look forward to continuing our collaboration with Clarity and also exploring therapeutic benefits of the $^{67}$Cu SAR-Bombesin agent for this large patient population where, unfortunately, very few treatment options are available at present."

**Clarity's Executive Chairman, Dr Alan Taylor, commented,** "The promising data we are generating on our SAR-Bombesin product has already resulted in the improvements to the management of prostate cancer for patients with PSMA-negative lesions or low PSMA expression in their tumours. We envision that SAR-Bombesin will not only be used as a stand-alone product for diagnosing and treating prostate cancer, but also in combination with PSMA agents to identify and treat both PSMA as well as GRPr expressing tumours for the most optimal therapeutic outcome for these patients.

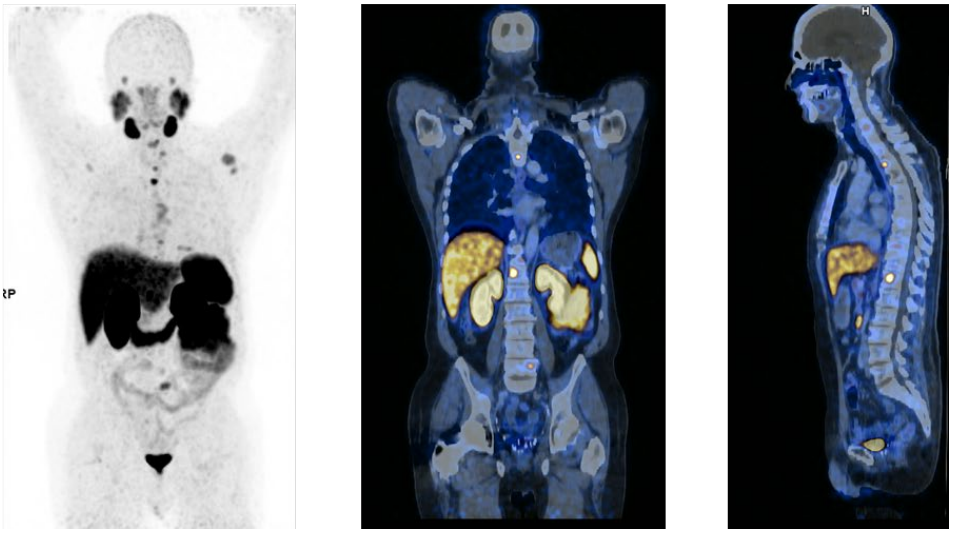
"We thank Prof Emmett and her team at St Vincent's Hospital for their hard work and dedication to our mutual goal of improving treatment outcomes for people with cancer. We look forward to a comprehensive data analysis from the BOP trial as we progress the development of this exciting theranostic agent in the US. We hope that the clinical benefits, combined with supply and manufacturing advantages of Targeted Copper Theranostics, will ensure that cancer patients can get their critical treatments on time and at a convenient location, representing a next-generation treatment paradigm focused on the needs of patients and their treating staff."

$^{64}$Cu SAR-Bombesin and $^{68}$Ga PSMA-11 images using PET (left) and PET/CT (middle/right) in a participant in the mCRPC cohort of the BOP trial. $^{64}$Cu SAR-BBN scans (top) show discordant detection of disease and additional metastatic lesions compared to $^{68}$Ga PSMA-11 (bottom).

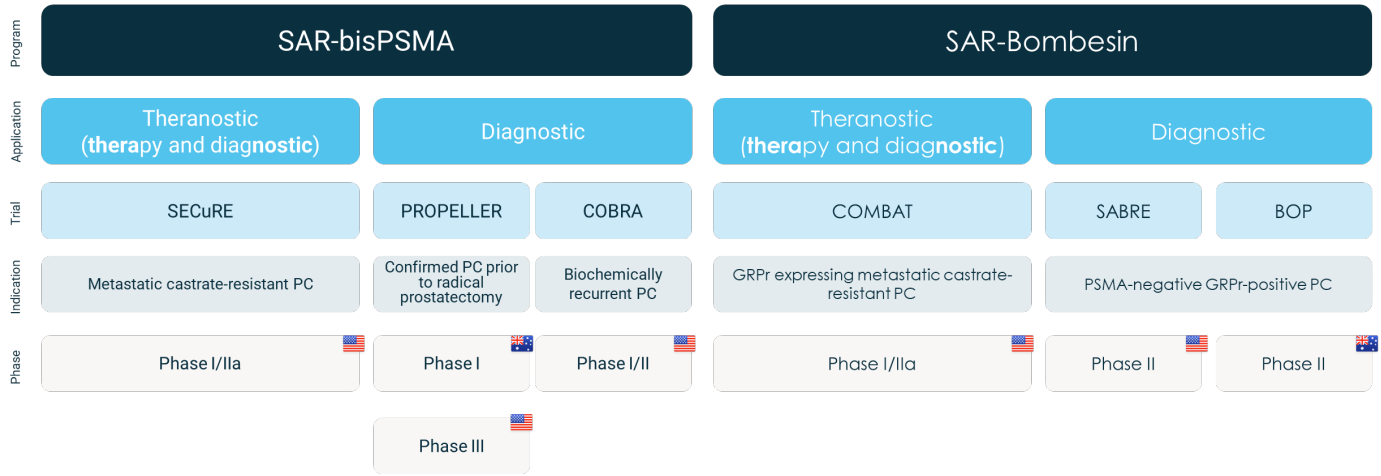
$^{64}$Cu-SAR-Bombesin




$^{68}$Ga-PSMA-11



## Overview of Clarity's Prostate Cancer Clinical Trial Program




## 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 $^{64}$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[2]. 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[3].

Approximately 20% of prostate cancers with BCR are PSMA-PET negative[4-7]. 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 TCTs based on its SAR technology platform for the treatment of children and adults with cancer.

***www.claritypharmaceuticals.com***

## References


1. ClinicalTrials.gov Identifier: NCT05613842, https://clinicaltrials.gov/ct2/show/NCT05613842
2. Markwalder R, Reubi JC. Gastrin-releasing peptide receptors in the human prostate: relation to neoplastic transformation. Cancer research. 1999;59(5):1152-1159.
3. Fleischmann A, Waser B, Reubi JC. High expression of gastrin-releasing peptide receptors in the vascular bed of urinary tract cancers: promising candidates for vascular targeting applications. Endocrine-related cancer. 2009;16(2):623-633.

4. Ananias HJ, van den Heuvel MC, Helfrich W, de Jong IJ. Expression of the gastrin-releasing peptide receptor, the prostate stem cell antigen and the prostate-specific membrane antigen in lymph node and bone metastases of prostate cancer. The Prostate. 2009;69(10):1101-1108.
5. Reubi JC, Wenger S, Schmuckli-Maurer J, Schaer JC, Gugger M. Bombesin receptor subtypes in human cancers: detection with the universal radioligand (125)I-[D-TYR(6), beta-ALA(11), PHE(13), NLE(14)] bombesin(6-14). Clin Cancer Res. 2002;8(4):1139-1146.
6. Sun B, Halmos G, Schally AV, Wang X, Martinez M. Presence of receptors for bombesin/gastrin-releasing peptide and mRNA for three receptor subtypes in human prostate cancers. The Prostate. 2000;42(4):295-303.
7. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries, https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.21660
8. American Cancer Society: Key Statistics for Prostate Cancer, https://www.cancer.org/cancer/prostate-cancer/about/key-statistics.html
9. Afshar-Oromieh A, Holland-Letz T, Giesel FL, et al. Diagnostic performance of $^{68}$Ga-PSMA-11 (HBED-CC) PET/CT in patients with recurrent prostate cancer: evaluation in 1007 patients. Eur J Nucl Med Mol Imaging. 2017 Aug;44(8):1258-1268.
10. Ferraro DA, Rüschoff JH, Muehlematter UJ, et al. Immunohistochemical PSMA expression patterns of primary prostate cancer tissue are associated with the detection rate of biochemical recurrence with $^{68}$Ga-PSMA-11-PET. Theranostics. 2020;10(14):6082-6094.
11. Baratto L, Song H, Duan H, et al. PSMA- and GRPR-Targeted PET: Results from 50 Patients with Biochemically Recurrent Prostate Cancer. J Nucl Med. 2021;62(11):1545-1549.
12. Mapelli P, Ghezzo S, Samanes Gajate AM, et al. $^{68}$Ga-PSMA and $^{68}$Ga-DOTA-RM2 PET/MRI in Recurrent Prostate Cancer: Diagnostic Performance and Association with Clinical and Histopathological Data. Cancers (Basel). 2022;14(2):334.

**For more information, please contact:**

**Clarity Pharmaceuticals**

Dr Alan Taylor
**Executive Chairman**
ataylor@claritypharm.com

Catherine Strong
**Investor/Media Relations**
cstrong@citadelmagnus.com
+61 406 759 268

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