

**ASX ANNOUNCEMENT**

13 September 2023

## BOP preliminary trial results presented at EANM 2023 conference

**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 favourable imaging data from the Phase II diagnostic investigator-initiated trial (IIT) of <sup>64</sup>Cu SAR-Bombesin in prostate cancer, BOP (NCT05613842)<sup>1</sup>.

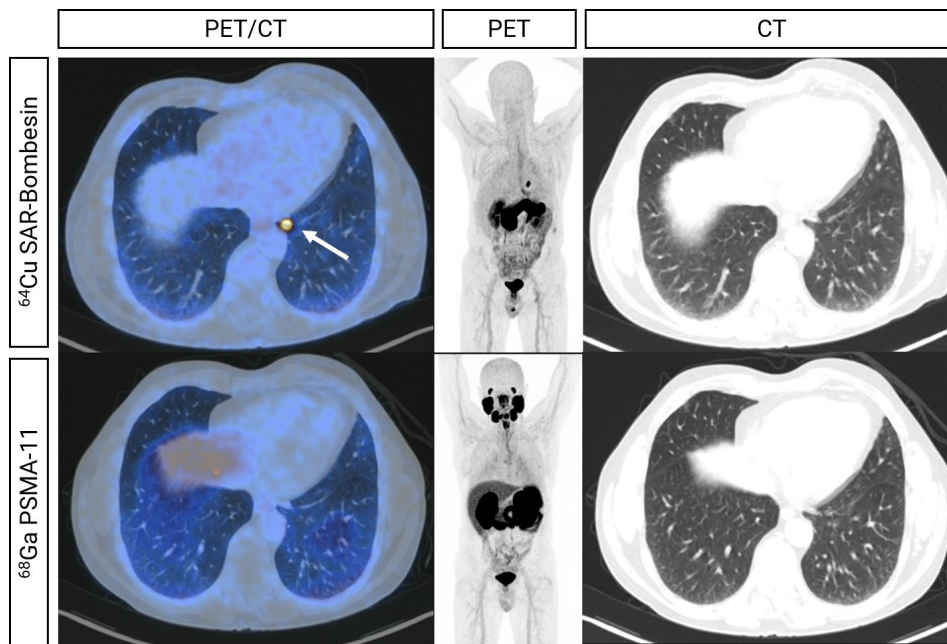
The BOP trial was led by Prof Louise Emmett at St Vincent’s Hospital, Sydney and it assessed the safety and diagnostic performance of <sup>64</sup>Cu SAR-Bombesin across two different groups of men:

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.

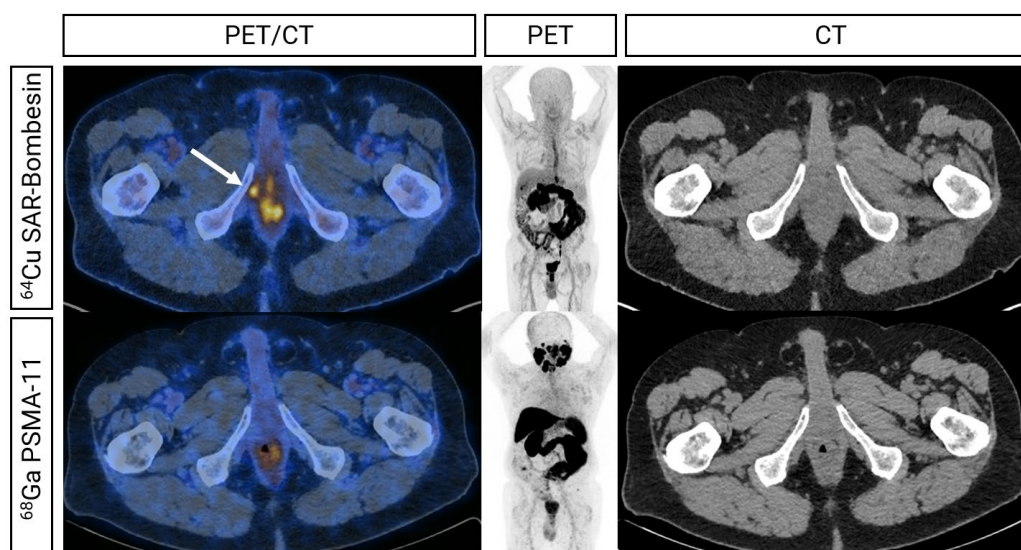
Study results from the first cohort (BCR) have been presented at the European Association of Nuclear Medicine (EANM) 2023 Congress in Vienna, Austria, one of the most prestigious conferences in the nuclear medicine field.

Demographics showed that most participants in the BCR cohort of the BOP trial had undergone radical prostatectomy (96%), a surgery to remove the entire prostate gland and surrounding lymph nodes, with Prostate Specific Antigen (PSA) doubling time of 4.2 months (range 2.8 – 7.5; PSA mean 0.69 ng/ml, range 0.28 – 2.45) prior to entering the study. PSA is a blood test where high levels of PSA may indicate the presence of prostate cancer.

Participants in the BOP trial received the mean dose of 210 MBq of <sup>64</sup>Cu SAR-Bombesin and imaged with Positron Emission Tomography (PET) at 1, 3 and 24 hours post-administration of the product. No adverse events from <sup>64</sup>Cu-SAR-Bombesin administration were reported. <sup>64</sup>Cu SAR-Bombesin PET avid disease was identified in over 30% of patients with negative or equivocal standard of care (SOC) PSMA PET (8/25, 32% detection rate).



*Figure 1 – Fused, MIP (Maximum Intensity Projection) and CT (Computed Tomography) (left to right) images from <sup>64</sup>Cu SAR-Bombesin (top) and PSMA (bottom) PET of a patient demonstrating a left subpleural lesion with <sup>64</sup>Cu SAR-Bombesin uptake (arrow) without SOC PSMA uptake. This patient underwent a lobectomy with histopathology demonstrating metastatic prostate cancer.*

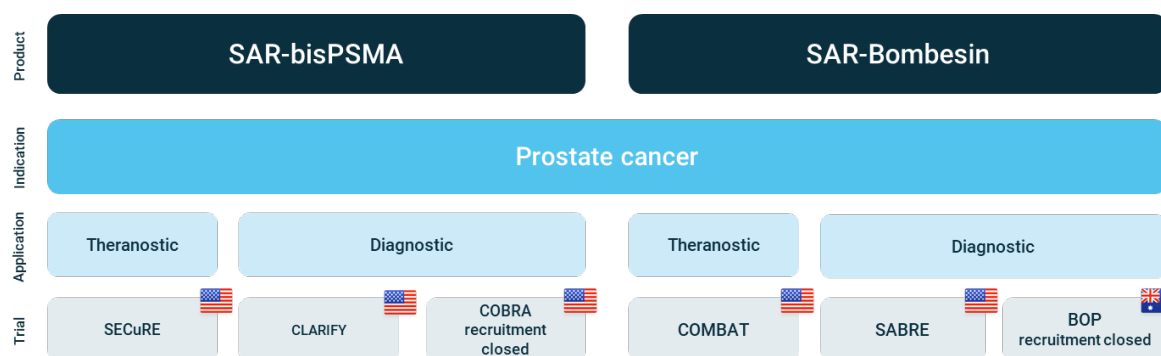


**Figure 2 – Fused, MIP and CT (left to right) images from <sup>64</sup>Cu SAR-Bombesin (top) and PSMA (bottom) PET of a patient demonstrating uptake at the right urethral anastomosis on <sup>64</sup>Cu SAR-Bombesin alone (arrow). This patient was managed with local radiotherapy with improvement in PSA post-treatment.**

**Clarity’s Executive Chairperson, Dr Alan Taylor, commented,** “What is most exciting about this data is the identification of lesions in the most difficult to treat patient group, who are negative on all other SOC imaging. This information arms clinicians with accurate diagnostic information and helps them determine the best course of treatment for their patients. In essence, for the patients that have had a positive SAR-Bombesin scan, this is the difference between having an incorrect negative cancer diagnosis leading to cancer progression and now having an effective treatment plan that may lead to long term remission. This patient-centric approach, reinforced by the flexibility in the timing of the scan, centralised product manufacture and its broad distribution to any imaging centre with a PET camera, would be a true paradigm shift in the management of prostate cancer. We are continuing to work diligently on the development of the SAR-Bombesin product in the US, including our Phase II SABRE trial (NCT05407311) as well as the theranostic Phase I/IIa COMBAT trial (NCT05633160), in order to make this product available to the patients who need it most and might not have any other diagnostic and therapeutic options available to them.”

**Prof Louise Emmett (St Vincent’s Hospital Sydney), Principal Investigator in the BOP trial, commented,** “We are pleased with the results we have generated in the BOP trial, which have shown that <sup>64</sup>Cu SAR-Bombesin can detect lesions in men with biochemically recurrent prostate cancer that are negative or equivocal on PSMA PET. We believe SAR-Bombesin has the potential to add value in biochemical recurrence of prostate cancer following definitive therapy. We look forward to continuing our collaboration with Clarity and also exploring the diagnostic and therapeutic benefits of SAR-Bombesin in not only prostate cancer which is PSMA negative, but also in other diseases such as breast cancer.”

### 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 up to 100% of prostate cancers, including prostate cancers that don't express PSMA (PSMA-negative)<sup>2-6</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.

<sup>64</sup>Cu SAR-Bombesin is an unregistered product. Individual results may not represent the overall safety and efficacy of the product. The data outlined in this announcement has not been assessed by health authorities such as the US Food and Drug Administration (FDA). A clinical development program is currently underway to assess the efficacy and safety of these products. There is no guarantee that these products will become commercially available.

## 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>7</sup>. 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<sup>8</sup>.

Approximately 20% of prostate cancers with BCR are PSMA-PET negative<sup>9-12</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)

## 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, Schaefer 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 68Ga-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 68Ga-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, Ghezzi S, Samanes Gajate AM, et al. 68Ga-PSMA and 68Ga-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](mailto:ataylor@claritypharm.com)

Catherine Strong

**Investor/Media Relations**

[cstrong@citadelmagnus.com](mailto:cstrong@citadelmagnus.com)

+61 406 759 268

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