

ASX MEDIA RELEASE

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## First participant imaged in Phase II SAR-Bombesin prostate cancer trial in the US

**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 it has successfully imaged its first participant in the US-based diagnostic <sup>64</sup>Cu SAR-Bombesin trial (SABRE [NCT05407311](#))<sup>1</sup> for patients with PSMA-negative prostate cancer.

**SABRE** (Copper-64 SAR-BisPSMA in Biochemical Recurrence of prostate cancer) is a Phase II Positron Emission Tomography (PET) imaging trial of participants with PSMA-negative biochemical recurrence (BCR) of prostate cancer following definitive therapy. It is a multi-centre, single arm, non-randomised, open-label trial of <sup>64</sup>Cu-labelled SAR-Bombesin in 50 participants. The primary objectives of the trial are to investigate the safety and tolerability of the product as well as its ability to correctly detect recurrence of prostate cancer.

**Dr Luke Nordquist, CEO, Urologic Medical Oncologist and Principal Investigator at the Urology Cancer Center and GU Research Network in Omaha, Nebraska, commented,** "We are very excited to have recruited and imaged the first participant in this trial which will explore the clinical benefits of the novel SAR-Bombesin agent. Based on the promising preclinical and clinical data to date, SAR-Bombesin shows great potential for improving the diagnosis and treatment for not only patients with prostate cancer that are PSMA negative, but also across broader prostate cancer indications.

"SABRE is the third trial with Clarity's Targeted Copper Theranostics (TCTs) that GURN is recruiting into. This momentum is underpinned by our belief that the TCTs are the next-generation products that will enable the radiopharmaceutical field to overcome the manufacturing and supply chain challenges associated with the current products in the market and facilitate the expansion of radiopharmaceuticals into the large global oncology market. We look forward to generating data from the trial to validate the potential clinical benefits for large patient populations and improve patient care."

**Clarity's Executive Chairman, Dr Alan Taylor, commented,** "We are very excited to progress the SABRE trial in the United States as we are already seeing an improved treatment paradigm in the management of PSMA-negative disease for patients with SAR-Bombesin who were imaged under the Therapeutic Goods Agency's Special Access Scheme in Australia<sup>2</sup>.

"Given the data to date indicates the potential diagnostic and therapeutic benefits of SAR-Bombesin, we look forward to generating further evidence as we accelerate the product to market. Subject to the outcome of the SABRE trial, Clarity is planning to launch a pivotal Phase III diagnostic trial for first product approvals in the US. We are also preparing to run a theranostic trial with an Investigational New Drug (IND) application scheduled for submission to the US Food and Drug Administration (FDA) later this year. We look forward to progressing our SAR-Bombesin program and potentially providing a large patient population with accurate and precise detection and treatment of their prostate 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)<sup>3-7</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>8</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>9</sup>.

Approximately 20% of prostate cancers with BCR are PSMA-PET negative<sup>10-13</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.

### 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: NCT05407311 <<https://clinicaltrials.gov/ct2/show/NCT05407311>>
2. Niketh J, Bao H, Emmett, L. <sup>64</sup>Cu-SAR-Bombesin PET-CT for the detection of biochemically recurrent PSMA-PET negative prostate cancer: a case series. 2022 ANZUP Annual Scientific Meeting. Program of Abstracts. Vol 18. Issue S1. P55. <<https://doi.org/10.1111/ajco.13827>>
3. Markwalder R, Reubi JC. Gastrin-releasing peptide receptors in the human prostate: relation to neoplastic transformation. Cancer research. 1999;59(5):1152-1159.
4. 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.
5. 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.

6. 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.
7. 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.
8. 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>>
9. American Cancer Society, Cancer Statistics Center, <[https://cancerstatisticscenter.cancer.org/?\\_ga=2.79808020.284532473.1620009137-1916069442.1615761164#!/cancer-site/Prostate](https://cancerstatisticscenter.cancer.org/?_ga=2.79808020.284532473.1620009137-1916069442.1615761164#!/cancer-site/Prostate)>
10. Afshar-Oromieh A, Holland-Letz T, Giesel FL, et al. Diagnostic performance of <sup>68</sup>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.
11. 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 <sup>68</sup>Ga-PSMA-11-PET. Theranostics. 2020;10(14):6082-6094.
12. 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.
13. Mapelli P, Ghezzi S, Samanes Gajate AM, et al. <sup>68</sup>Ga-PSMA and <sup>68</sup>Ga-DOTA-RM2 PET/MRI in Recurrent Prostate Cancer: Diagnostic Performance and Association with Clinical and Histopathological Data. Cancers (Basel). 2022;14(2):334.

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