

**ASX ANNOUNCEMENT**

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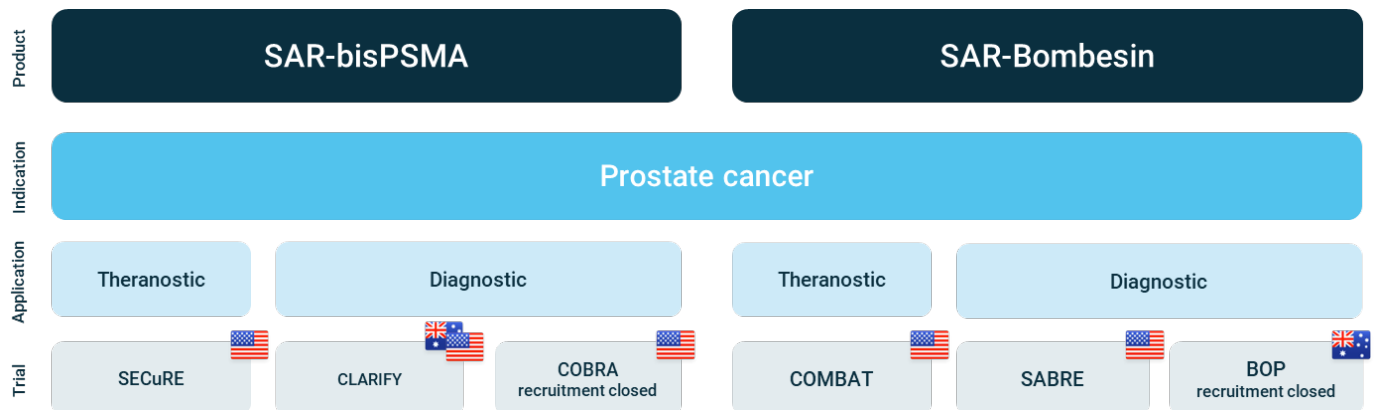
# First patient treated with Cu-67 SAR-Bombesin in theranostic prostate cancer trial

**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 dosing of the first patient in its theranostic <sup>64</sup>Cu/<sup>67</sup>Cu SAR-Bombesin Phase I/II trial in metastatic castrate resistant prostate cancer (mCRPC). No issues were observed during the administration of 6GBq of <sup>67</sup>Cu SAR-Bombesin and the participant continues to be followed for further safety and efficacy assessments as per protocol.

**COMBAT**, which derives from "**C**opper-67 **S**AR-**B**ombesin in metastatic castrate resistant prostate cancer (NCT05633160)<sup>1</sup> is a dose escalation and cohort expansion trial for up to 38 participants. <sup>64</sup>Cu SAR-Bombesin is used to visualise gastrin-releasing peptide receptor (GRPr)-expressing lesions and select candidates for subsequent <sup>67</sup>Cu SAR-Bombesin therapy. The aim for the trial is to determine the safety and efficacy of <sup>67</sup>Cu SAR-Bombesin in participants with GRPr expressing mCRPC who are ineligible for therapy with <sup>177</sup>Lu PSMA-617. These patients are unlikely to benefit from prostate-specific membrane antigen (PSMA)-targeted agents and represent a significant unmet need for both imaging and therapy. Doses of up to 14GBq of <sup>67</sup>Cu SAR-Bombesin, in up to four cycles, are planned to be investigated in this trial (pending safety reviews).

**Clarity's Executive Chairperson, Dr Alan Taylor, commented,** "SAR-Bombesin has already resulted in improvements to the management of prostate cancer for patients with PSMA-negative or low PSMA expressing lesions through diagnostic trials and we hope to confirm its safety and efficacy in this theranostic trial. We look forward to progressing the COMBAT trial and building on the compelling data from our preclinical and clinical studies to date. Combined with the logistical and manufacturing benefits of Targeted Copper Theranostics and with commercial quantities of the <sup>67</sup>Cu radioisotope now being routinely produced domestically in the US, we see a clear path to bringing SAR-Bombesin and SAR-bisPSMA to the prostate cancer patient population in need of novel treatments."

## 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 and <sup>67</sup>Cu SAR-Bombesin are unregistered products. Individual results may not represent the overall safety and efficacy of the products. 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 25% of mCRPC patients have low or no uptake of a PSMA-targeting tracer.<sup>9</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

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