

**ASX ANNOUNCEMENT**

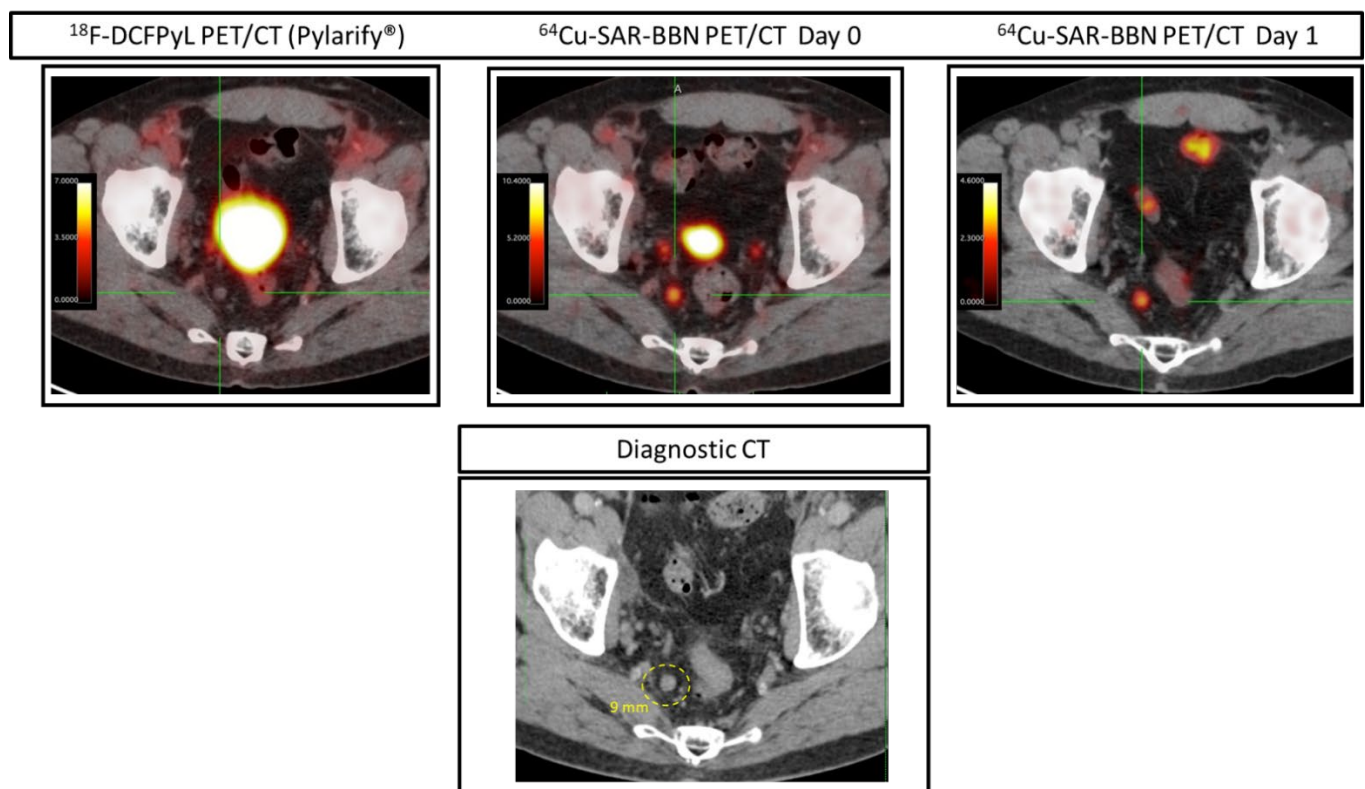
24 July 2023

## Clarity reaches 50% recruitment milestone for Phase II SABRE 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 Phase II US-based diagnostic <sup>64</sup>Cu SAR-Bombesin trial (SABRE NCT05407311)<sup>1</sup> for patients with prostate cancer has reached its fifty percent recruitment milestone, with 25 out of 50 participants enrolled and imaged.

**SABRE** (Copper-64 SAR-Bombesin 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 safety and tolerability of the product as well as its ability to correctly detect recurrence of prostate cancer.

**Figure 1. Single pelvic lymph node uptake seen on <sup>64</sup>Cu SAR-Bombesin on both Day 0 and Day 1. A subsequent biopsy, performed and assessed locally by the study site, has confirmed prostate cancer. Participant has entered the follow-up period for protocol.**



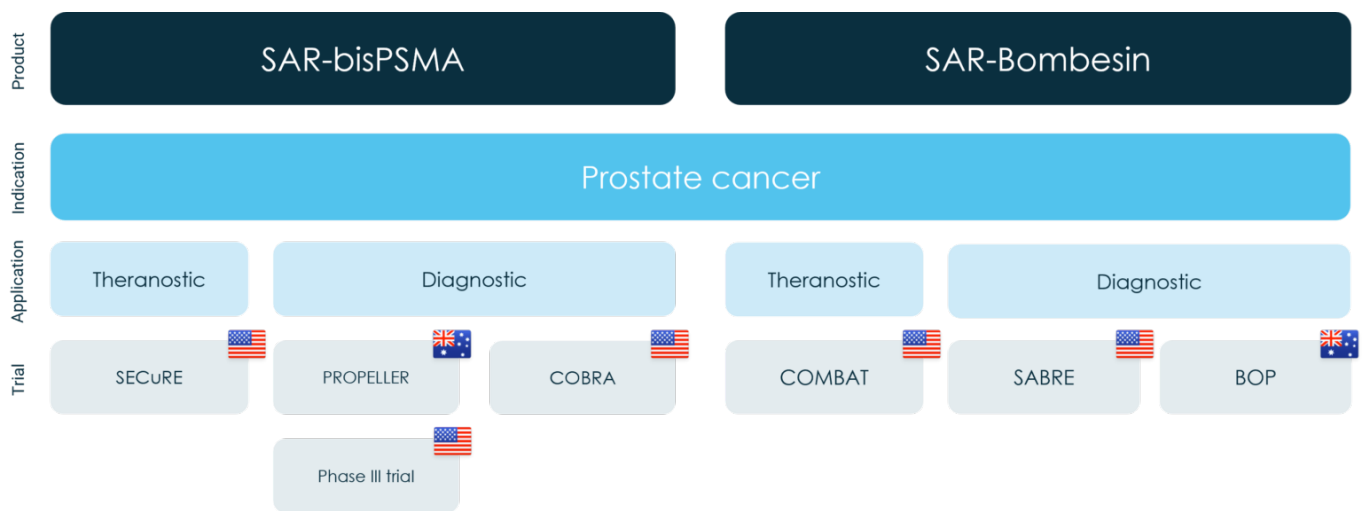
**Andrei Iagaru, MD, the Lead Principal Investigator for the trial, commented,** “We have been working on Bombesin for many years now and I am very excited with the progress of the SABRE trial and the continued exploration and validation of the clinical benefits associated with the SAR-Bombesin agent. It gives hope to clinicians and patients who have no other suitable diagnostic options available due to their cancers having low or no PSMA expression. Being able to visualise the disease can change the entire treatment paradigm for these patients. Once we can see the cancer, clinicians can then find the most suitable therapeutic regiment to maximise treatment outcomes. Based on the promising preclinical and clinical data to date, SAR-Bombesin is an exciting new product for better managing these

patients that have few options at present in the face of a devastating diagnosis. We look forward to recruiting the remaining 25 patients in the trial and further analysing the trial data.”

**Clarity’s Executive Chairman, Dr Alan Taylor, commented,** “We continue to build significant positive data on our SAR-Bombesin product. In addition to the SABRE trial, we are actively recruiting participants to our theranostic trial, COMBAT, and have recently finished recruitment into an investigator initiated Phase II diagnostic trial, BOP, with this product. Subject to the outcome of the SABRE trial, Clarity is planning to launch a pivotal Phase III diagnostic trial for first product approval in the US.

“SAR-Bombesin has already resulted in improvements to the management of prostate cancer for patients that are PSMA-negative or have low PSMA expressing tumours and we hope to confirm its safety and efficacy in our clinical programs. We look forward to progressing the development of SAR-Bombesin and potentially providing a large patient population with accurate and precise detection and treatment of their prostate 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 approximately 75-100% 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.

### 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 PC 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 TCTs based on its SAR technology platform for the treatment of children and adults with cancer.

[www.claritypharmaceuticals.com](http://www.claritypharmaceuticals.com)

## References

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