

ASX MEDIA RELEASE

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Clarity strengthens patent protection of SAR-bisPSMA

Clarity Pharmaceuticals (ASX: CU6) (“Clarity” or the “Company”), an Australian-based clinical stage radiopharmaceutical company developing next-generation products to address the growing need in oncology, is pleased to announce that the patent application covering formulations of Clarity’s optimised Prostate Specific Membrane Antigen (PSMA) targeting agent, SAR-bisPSMA, has entered the national phase in multiple jurisdictions, including the USA, Europe and China. SAR-bisPSMA is a Targeted Copper Theranostic (TCT) for diagnosis and treatment of prostate cancer. A patent including claims covering the SAR-bisPSMA compound was recently granted in the USA, with an expiry date of 5 June 2038.

SAR-bisPSMA has entered two clinical trials in July 2021:

- **SECURE trial in the US:** A Phase I/IIa Theranostic Study of ⁶⁴Cu-SAR-bisPSMA and ⁶⁷Cu-SAR-bisPSMA for Identification and Treatment of PSMA-expressing Metastatic Castrate Resistant Prostate Cancer ([NCT04868604](https://clinicaltrials.gov/ct2/show/NCT04868604))¹
- **PROPELLER trial in Australia:** Positron Emission Tomography Imaging of Participants With Confirmed Prostate Cancer Using ⁶⁴Cu-SAR-bisPSMA: A Multi-Centre, Blinded Review, Dose Ranging Phase I Study ([NCT04839367](https://clinicaltrials.gov/ct2/show/NCT04839367))²

The prostate cancer market is a key focus for Clarity and the company is rapidly hitting key milestones in the development of SAR-bisPSMA with the recent completion of patient recruitment into the dosimetry phase of the SECURE trial and ongoing recruitment in the PROPELLER trial.

Clarity’s Executive Chairman, Dr Alan Taylor, commented, “We are very pleased with the evolving patent protection of one of our core products, SAR-bisPSMA, with the entry of the international application into the National Phase around the world. This further strengthens our position in the radiopharmaceutical field as we progress the clinical development of this asset in the US and Australia. This milestone is testament to Clarity’s strong emphasis on Intellectual Property (IP) protection since the inception of the company with a patent strategy designed to cover the SAR Technology platform as well as radiopharmaceutical products and the “Discovery Program” focused on developing new products and new IP for a range of cancer indications. This aggressive patent strategy allows us to gain strong protection with any targeting agent and expand our product pipeline, gaining a sustainable competitive advantage in this field.”

This broad and deep patent strategy has resulted in the allowance and grant of a number of Clarity’s patent applications for key compounds in major jurisdictions, including patents for SARTATE™ and SAR-Bombesin. Clarity continues to extend its patent position with the recent filing of new provisional applications.

Dr Alan Taylor said, “Clarity’s patenting strategy enables us to successfully leverage our IP to develop a pipeline of next-generation radiopharmaceuticals and we are determined to fully exploit the broad coverage of the platform to continue pursuing our ultimate goal of developing better treatments for children and adults with cancer.”

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

About Prostate Cancer

Prostate cancer is the second most common cancer diagnosed in men globally and the fifth leading cause of cancer death worldwide³. In 2021, the National Cancer Institute estimated 248,530 new cases of prostate cancer in the US and around 34,130 deaths from the disease⁴. Annually, there are around ~34,000 men in the US who are diagnosed with mCRCP⁵, ~90% of whom have tumours which express PSMA⁶.

References

1. ClinicalTrials.gov Identifier: NCT04868604 <https://clinicaltrials.gov/ct2/show/NCT04868604>
2. ClinicalTrials.gov Identifier: NCT04839367 <https://clinicaltrials.gov/ct2/show/NCT04839367>
3. 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>

4. American Cancer Society, Cancer Statistics Center,
https://cancerstatisticscenter.cancer.org/?_ga=2.79808020.284532473.1620009137-1916069442.1615761164#!/cancer-site/Prostate
5. American Cancer Society, Cancer Statistics Center,
https://cancerstatisticscenter.cancer.org/?_ga=2.79808020.284532473.1620009137-1916069442.1615761164#!/cancer-site/Prostate
6. D. A. Silver, I. Pellicer, W. R. Fair, W. D. Heston and C. Cordon-Cardo 1997. "Prostate-specific membrane antigen expression in normal and malignant human tissues." Clinical Cancer Research. vol. 3, 81-85, January 1997

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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/