

ASX MEDIA RELEASE

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## Clarity and Evergreen expand Targeted Copper Theranostics manufacturing

**Clarity Pharmaceuticals** (ASX: CU6) (“Clarity” or the “Company”), a clinical-stage radiopharmaceutical company developing next-generation products to address the growing needs in oncology, and Evergreen Theragnostics, Inc. (“Evergreen”), a radiopharmaceutical contract development and manufacturing organisation, are pleased to announce that the companies have expanded their Targeted Copper Theranostics (TCTs) manufacturing agreement to include next-generation therapeutic products based on <sup>67</sup>Cu SAR-Bombesin for Clarity’s planned theranostic trial in the US.

The new agreement, effective as of today, builds on Clarity and Evergreen’s existing TCTs manufacturing agreement, entered into on 30 September 2021. Evergreen will now centrally manufacture and distribute the following products from its state-of-the-art facility in Springfield, New Jersey, USA:

- <sup>67</sup>Cu and <sup>64</sup>Cu SAR-Bombesin for Clarity’s planned theranostic trial in PSMA-negative GRPr-positive prostate cancer in the US
- <sup>64</sup>Cu SAR-Bombesin for Clarity’s stand-alone diagnostic trial in PSMA-negative GRPr-positive prostate cancer in the US
- <sup>67</sup>Cu SARTATE™ for Clarity’s theranostic neuroblastoma trial which is currently underway at multiple sites across the US

**Evergreen’s CEO, James Cook, commented,** “We are pleased to continue working together with Clarity on the manufacturing and supply of the TCT platform of products as they enter new, exciting trials in the US. TCTs are uniquely suited for central manufacture with optimal shelf-lives for distribution across North America and utilise a simple room-temperature manufacturing process. We look forward to enhancing patient access to these innovative radiopharmaceuticals together with Clarity and are excited to support the roll-out of the next-generation clinical development program with the common goal of improving treatment outcomes for children and adults with cancer.”

**Clarity’s Executive Chairman, Dr Alan Taylor, commented,** “Clarity is excited to be progressing the TCT platform with our third therapeutic product, <sup>67</sup>Cu SAR-Bombesin. We plan to file an Investigational New Drug (IND) application with the US Food and Drug Administration (FDA) for a trial with this product shortly. SAR-Bombesin is a promising agent for identification and treatment of prostate cancers that do not express PSMA and are thus ineligible for PSMA-based imaging and therapy, a segment with a high unmet need.

“We have experienced strong demand from clinicians in Australia for the diagnostic product already. Both human trial data as well as recently published preclinical data demonstrate high retention in tumour and rapid clearance from non-target organs over 24 hours, which supports the development of SAR-Bombesin as a therapy. We continue to enhance our reliable and scalable manufacturing and logistics footprint for our TCT products together with Evergreen as we further progress our clinical development efforts in the US,” **said Dr Taylor.**

### 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>1-5</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>6</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>7</sup>.

### **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)

### **About Evergreen Theragnostics**

Evergreen Theragnostics, established in 2019, is a leading US-based radiopharmaceutical Contract Development and Manufacturing Organization (CDMO). With a state-of-the-art global GMP facility opened in 2021, Evergreen provides highly reliable manufacturing services for therapeutic and centrally distributed diagnostic radiopharmaceuticals, from early development through commercialization. The company was founded by a team that brings a strong track record in theragnostic radiopharmaceutical commercialization, manufacturing process development, and regulatory affairs management.

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

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