

ASX MEDIA RELEASE

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## Clarity expands manufacturing capabilities for its <sup>64</sup>Cu SAR-bisPSMA clinical programs

**Clarity Pharmaceuticals** (ASX: CU6) (“Clarity” or the “Company”), a clinical-stage radiopharmaceutical company developing next-generation products to address the growing needs in oncology, has signed a supply agreement with 3D Imaging LLC. (3DI), a Contract Development and Manufacturing Organisation (CDMO), covering Clarity’s diagnostic <sup>64</sup>Cu SAR-bisPSMA product.

The new agreement, effective on August 11<sup>th</sup>, 2022, enables increased production and will create excess capacity in the supply of Clarity’s differentiated PSMA product in advance of two potential diagnostic Phase III trials in the US, ensuring reliable and seamless supply. 3DI will centrally manufacture and distribute the <sup>64</sup>Cu SAR-bisPSMA products from its facility in Little Rock, Arkansas, USA, located close to the Global FedEx hub.

**Clarity’s Executive Chairman, Dr Alan Taylor, commented,** “We are excited to continue strengthening Clarity’s supply and manufacturing efforts and distinguishing ourselves from the current generation of radiopharmaceuticals that have many logistical limitations due to very short half-lives. In a field with all too many unforeseen product supply limitations and outages, we are building a reliable supply network with excess capacity.”

Clarity’s <sup>64</sup>Cu-based products can be centrally manufactured on existing cyclotrons and distributed broadly with a widespread geographical reach due to a significantly longer shelf-life of Clarity’s Targeted Copper Theranostics (TCT) products. A single cyclotron can supply <sup>64</sup>Cu for the entire Phase III diagnostic clinical program.

“Clarity is overlaying several cyclotrons and manufacturers to enable TCTs’ future expansion into the larger commercial setting. By building a reliable and accessible supply chain that is consistent with that of the “big pharma” oncology model, Clarity aims to create a significant competitive advantage as we continue to pursue our ultimate goal of improving treatment outcomes for children and adults with cancer.” **said Dr Taylor.**

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

### About SAR-bisPSMA

SAR-bisPSMA derives its name from the word “bis”, which reflects a novel approach of connecting two prostate-specific membrane antigen (PSMA) binding motifs to Clarity’s proprietary sarcophagene (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-bisPSMA 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>1</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>2</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 3D Imaging LLC

3D Imaging LLC is a CDMO specializing in radiopharmaceutical development and supplying cyclotron produced radionuclides such as Cu-64, F-18, Zr-89, and I-124. Founded in 2001, 3DI moved to Little Rock, AR in 2007 and opened its current custom built cGMP facility with over 10,000 sq ft of office and laboratory space in 2018. Their facility operates a Siemens Eclipse 11 MeV dual beam cyclotron and associated hot cells dedicated to positron emitting radionuclides and custom radiopharmaceutical production.

<https://www.3dimagingllc.com/>

## References

1. 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>
2. 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)

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