

**ASX ANNOUNCEMENT**

4 April 2024

# Clarity enters into Cu-67 SAR-bisPSMA Clinical Supply Agreement with NorthStar supporting late-stage therapy trials

**Highlights**

- **New Clinical Supply Agreement with NorthStar for the production of <sup>67</sup>Cu-SAR-bisPSMA drug product ensures seamless product supply as Clarity plans for upcoming pivotal therapy trials.**
- **Uniquely provides large-scale manufacturing of both the therapeutic isotope (copper-67) and cGMP radiopharmaceutical product in the United States ready for shipment to clinical sites.**
- **Integrated manufacturing offers significant logistical, manufacturing and environmental advantages, including simplified logistics with minimal shipping requirements, efficient utilisation of the radioisotope and reduced carbon footprint.**
- **Agreement builds on the existing copper-67 supply agreement with NorthStar, signed in 2021.**

**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 signing of a Clinical Supply Agreement with NorthStar Medical Radioisotopes, LLC (NorthStar) for the production of <sup>67</sup>Cu-SAR-bisPSMA drug product for Phase I/II and Phase III trials.

**Clarity's Executive Chairperson, Dr Alan Taylor, commented,** "This important step is yet another differentiating factor that helps Clarity clearly stand out from the rest of the radiopharmaceutical market, making it possible to have therapeutic isotope supply and product manufacture at the same site. We have seen in the past the logistical challenges associated with the separation of radioisotope and final drug product manufacturing with lutetium-177 (Lu-177 or <sup>177</sup>Lu) based therapies as it causes delays and inefficiencies, ultimately affecting care for oncology patients waiting for their treatments. Alpha-emitter therapies, such as those involving actinium-225 (Ac-225 or <sup>225</sup>Ac) and lead-212 (Pb-212 or <sup>212</sup>Pb), are generating interest, but their commercial supply chains are still in the early development phase, and they are currently very difficult to source. These isotopes are also yet to show safety and efficacy in late-stage trials, as opposed to beta emitters, like Cu-67, that have a long history of effectiveness in treating solid tumors.

"The shift away from limited nuclear reactor-based supply, where even today there is an important facility down in Europe due to maintenance issues, is vital in order for radiopharmaceuticals to grow sustainably into the large oncology sector. Copper-67 (Cu-67 or <sup>67</sup>Cu) and Targeted Copper Theranostics (TCTs) can now be manufactured and shipped from a single location, a unique feature of Cu-67, due to its ability to be manufactured using electron accelerators.

"By employing TCTs based on Cu-67, Clarity can avoid many of the drawbacks of other therapeutic isotopes, including alpha- and other beta-based therapies. Our TCT therapy programs require only electricity and zinc to make Cu-67, which is now routinely produced in large volumes in the US. The isotope manufacturing is completely modular and scalable, providing significant advantages to increase production in a timely manner. Other advantages of TCTs, such as room temperature manufacturing, reduce the likelihood of batch failures that lead to common supply issues. The fully integrated supply chain of TCTs from production of the isotope to ready-to-use radiopharmaceuticals is unique to Clarity and our platform of therapeutic products under development."

"Given our outstanding clinical trial data to date, we are very excited to secure the supply of Cu-67 and final drug products for the trials with <sup>67</sup>Cu-SAR-bisPSMA in prostate cancer as we continue building a sustainable future for radiopharmaceuticals towards our ultimate goal of better treating children and adults with cancer."

The overarching Master Service Agreement and associated Clinical Supply Agreement are effective immediately. The initial supply from NorthStar is expected to occur before the end of calendar year 2024. The Master Services Agreement is for an initial period of 4 years and the Clinical Supply Agreement is for an initial period of 4 years. Cancellation provisions are at industry standard rates.

### **About SAR Technology**

Despite the unique benefits of Cu-67 as a therapeutic isotope for radiopharmaceuticals, historically, the lack of an effective copper chelating technology has limited the clinical development of Cu-67 products and subsequent commercial production of Cu-67. Clarity's proprietary copper-chelating technology, called "sarcophagine" or SAR Technology, has enabled it to advance the TCT product pipeline into a range of theranostic clinical trials that use copper-64 (Cu-64 or <sup>64</sup>Cu) for diagnostic imaging and Cu-67 for therapy. Clarity is currently progressing three key product areas, SAR-bisPSMA, SAR-Bombesin and SARTATE, with three theranostic and four diagnostic clinical trials with a focus on prostate cancer indications.

### **About SAR-bisPSMA**

SAR-bisPSMA derives its name from the word "bis", which reflects a novel approach of connecting two PSMA-targeting agents to 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-bisPSMA is a 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-bisPSMA and <sup>67</sup>Cu-SAR-bisPSMA are unregistered 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 NorthStar Medical Radioisotopes, LLC**

NorthStar Medical Radioisotopes is a commercial-stage radiopharmaceutical company at the forefront of advancing patient care by utilizing novel technologies to produce commercial-scale radioisotopes that, once attached to a molecule, have the ability to detect and treat cancer and other serious diseases. NorthStar's expanding industry-leading position in the emerging field of radiopharmaceutical therapy is supported by its unique capabilities in the sophisticated production of radioisotopes, proven management team, and state-of-the-art, environmentally preferable technologies. NorthStar routinely produces copper-67 (Cu-67) and is poised to be the first commercial-scale producer of non-carrier-added (n.c.a.) actinium-225 (Ac-225). The Company's Radiopharmaceutical Contract Development and Manufacturing Organization (CDMO) services unit provides customized service offerings and specialized radiopharmaceutical expertise to help biopharmaceutical companies rapidly advance their development and commercial programs.

For more information about NorthStar's comprehensive portfolio and patient-focused services, visit:

<http://www.northstarm.com>

### **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)

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