

ASX ANNOUNCEMENT

11 November 2024

Clarity and Nucleus RadioPharma sign Master Services Agreement and Cu-67 SAR-bisPSMA Clinical Supply Agreement

Highlights

- Nucleus RadioPharma will manufacture the ⁶⁷Cu-SAR-bisPSMA drug product at their new state-of-the-art facility in Rochester, MN.
- The Master Services Agreement (MSA) and Clinical Supply Agreement with Nucleus RadioPharma complement the existing agreement with NorthStar Medical Radioisotopes, LLC (NorthStar) for ⁶⁷Cu-SAR-bisPSMA production to expand drug manufacturing in anticipation of recruitment demand for Phase II and III trials of this product.
- Nucleus RadioPharma will first supply ⁶⁷Cu-SAR-bisPSMA into the cohort expansion phase of the SECuRE trial, expected to commence in early 2025.
- Nucleus RadioPharma recently announced an expansion plan to build additional manufacturing capacity in Arizona and Pennsylvania. Both locations are covered under this MSA, providing additional manufacturing capacity in the future for Phase III trials and commercialisation.

Clarity Pharmaceuticals (ASX: CU6) (“Clarity” or “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 it has entered into an MSA and Clinical Manufacturing Agreement for ⁶⁷Cu-SAR-bisPSMA with Nucleus RadioPharma, an innovative contract development and manufacturing organisation (CDMO) in the radiopharmaceutical industry, dedicated to the development and manufacturing of targeted radiotherapies.

This agreement builds on the earlier MSA and Clinical Supply Agreements with NorthStar for the production of ⁶⁷Cu-SAR-bisPSMA¹, allowing Clarity to continue building supply chain capacity ahead of a Phase III trial and commercialisation with this product.

Nucleus RadioPharma’s facility in Minnesota enables ⁶⁷Cu-SAR-bisPSMA manufacturing and distribution to all 50 states in the U.S. Their recently announced expansion plans for building additional manufacturing capacity in Arizona and Pennsylvania² are also in line with the timelines for development of Clarity’s ⁶⁷Cu-SAR-bisPSMA product, ensuring broad drug supply throughout the U.S.

Clarity’s Executive Chairperson, Dr Alan Taylor, commented, “We continue to strengthen our manufacturing network, ensuring prostate cancer patients in need of novel radiopharmaceutical treatments can get access to what we believe is a best-in-class product, on time and on demand. We have seen excellent data from the SECuRE³ trial and in case studies as part of the U.S. Food and Drug Administration (FDA) Expanded Access Program (EAP) with ⁶⁷Cu-SAR-bisPSMA and look forward to progressing the development of this important therapy to address the large unmet need in prostate cancer care.

“The strong demand from investigators for ⁶⁷Cu-SAR-bisPSMA and our accelerating pace of the SECuRE trial recruitment make this the right time to invest in additional manufacturing capacity. Our long-standing relationship with NorthStar has put us in a very unique position in radiopharmaceuticals, having both the therapeutic isotope and finished product manufactured at one site. We have seen the failures in the supply of Pluvicto® by Novartis where vulnerable patients were left waiting for their treatments⁴⁻⁵ and have learnt from these mistakes.

“At Clarity, we know that employing a layered supply strategy in anticipation of future demand is essential in radiopharmaceuticals. The use of the true theranostic pair, copper-64 and copper-67, allows for a readily scalable

approach to product manufacture, which stands in stark contrast to currently used isotopes, such as gallium-68, fluorine-18 and lutetium-177, where supply and logistical complications are common. As we continue to progress our development of Targeted Copper Theranostics (TCTs) and scale our supply in support of later-phase clinical trials and eventual commercialisation, we intend to make logistical interruptions affecting patient care a thing of the past.”

Nucleus RadioPharma’s Chief Scientific Officer, Dr Geoffrey Johnson, commented, “I am excited to continue my collaboration with Clarity on the development of its SAR-bisPSMA theranostic product. Being a Principal Investigator on the SECuRE trial, I have seen first-hand how my patients have benefited from the ⁶⁷Cu-SAR-bisPSMA therapy. I am now pleased to support the development of this product on the supply chain side as well and that Nucleus RadioPharma will be producing doses of this novel drug for patients in the SECuRE trial and beyond as it continues to generate strong data. Having the therapeutic copper-67 isotope produced domestically on purpose-built electron accelerators allows for reliable and scalable supply, free from the challenges of other therapeutic isotopes at this time, and Nucleus RadioPharma’s location in Rochester, MN allows seamless access to prestigious medical centres in the vicinity.”

The Master Services Agreement and Clinical Supply Agreement are effective as of 8 November 2024 and are for an initial period of 36 months. Cancellation and extension provisions are aligned with industry standard rates.

About Nucleus RadioPharma

Nucleus RadioPharma is an innovative CDMO in the radiopharmaceutical industry, dedicated to the development and manufacturing of targeted radiotherapies. With an emphasis on innovation and quality, the company provides an array of services, from formulation and analytical development to regulatory documentation and drug product manufacturing. Nucleus RadioPharma’s technology platforms are at the forefront of radiopharmaceutical research, designed to advance new therapies through clinical trials to commercialization. Recognized for its flexible approach, the company offers multiple onboarding points to accommodate innovators at various stages of their product lifecycle. Backed by Eclipse, Mayo Clinic, AstraZeneca, GE HealthCare, Echo Global, Fox Chase Cancer Center, Granger Management, Mercy Health, and University of Missouri, Nucleus RadioPharma stands well-supported by leading institutions and organizations committed to advancing healthcare through innovative solutions. Please visit nucleusrad.com and follow us on LinkedIn for more information.

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

For more information, please contact:

Clarity Pharmaceuticals

Dr Alan Taylor

Executive Chairperson

ataylor@claritypharm.com

Catherine Strong

Investor/Media Relations

c.strong@morrowsodali.com

+61 406 759 268

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