ASX ANNOUNCEMENT

17 June 2025

Clarity enters a Commercial Manufacturing Agreement for Cu-64 SAR-bisPSMA with SpectronRx

Highlights

- Clarity has entered into a Commercial Manufacturing Agreement with SpectronRx for ^{64}Cu-SAR-bisPSMA.
- SpectronRx's facility in Indiana will provide on-demand commercial-scale manufacturing of both copper-64 and ^{64}Cu-SAR-bisPSMA under one roof and enables distribution to all 50 states.
- SpectronRx will expand current production to up to 400,000 patient-ready doses of ^{64}Cu-SAR-bisPSMA annually at the Indiana facility by the time of commercialisation.
- The Agreement also includes an option to expand into similar additional sites, substantially increasing the manufacturing capacity of patient-ready doses of ^{64}Cu-SAR-bisPSMA in regional hubs spread throughout the US.
- The Commercial Supply Agreement supplements Clarity's current supply and manufacturing agreements for isotope and product, creating a multi-layered and abundant approach. This allows for nationally and regionally centralised as well as local production of isotope and final product enabled by the characteristics and optimal half-life of copper-64.

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 patients with cancer, is pleased to announce that it has entered into a Commercial Manufacturing Agreement with SpectronRx for Clarity's lead diagnostic product, ^{64}Cu-SAR-bisPSMA.

SpectronRx's facility in Indiana will provide on-demand commercial-scale manufacturing of both copper-64 and ^{64}Cu-SAR-bisPSMA under one roof and enable distribution to all 50 states. It is capable of producing up to 400,000 patient-ready doses of ^{64}Cu-SAR-bisPSMA annually from the one facility. Together with other supply and manufacturing agreements Clarity has entered to date, this Agreement substantially bolsters reliable, universal access to ^{64}Cu-SAR-bisPSMA in the US for a commercial rollout upon successful completion of Clarity's Phase III registrational trials with this product, CLARIFY[1] and AMPLIFY[2], and subsequent US Food and Drug Administration (FDA) New Drug Application (NDA) approval. The Commercial Supply Agreement with SpectronRx includes options to expand integrated ^{64}Cu-SAR-bisPSMA manufacturing to additional locations in the US, substantially increasing overall production capacity in the number of regional hubs throughout the US, providing a multi-layered and abundant supply approach, which is unique in the radiopharmaceutical space.

John Zehner, CEO of SpectronRx, highlighted the collaboration's potential to transform patient care, stating, "Partnering with Clarity marks a significant step forward in expanding access to radiopharmaceuticals and improving healthcare outcomes in the United States. SpectronRx's ability to reliably produce and distribute ^{64}Cu-SAR-bisPSMA further solidifies our position as a trusted manufacturing partner for radiopharmaceutical companies, ensuring timely access to essential diagnostic and therapeutic resources for patients and providers alike."

Clarity's Executive Chairperson, Dr Alan Taylor, commented, "This Agreement, combined with other supply and manufacturing agreements for isotope and finished product we have secured to date, ensures that we are ready to roll out large-scale manufacturing and distribution of ^{64}Cu-SAR-bisPSMA on day one of commercialisation. This will enable a seamless launch as soon as we have US FDA approval, allowing patients to get access to this next-generation diagnostic at any treatment facility in the US with a positron emission tomography (PET) scanner, 24 hours a day, 7 days a week.

"We look forward to fully leveraging the benefits of copper-64 and its optimal half-life of 12.7 hours to overcome the logistical issues inherent to current-generation diagnostics due to their reliance on isotopes with far shorter half-lives, namely gallium-68 and fluorine-18 (half-lives of around 1 hour and 2 hours, respectively). These short half-lives translate into short shelf-lives, constraining availability of these agents to a restricted number of locations at specific times, which often do not align to the clinical needs of the sites or the patients' needs. The gallium-68 supply chain requires large and continued capital investment to sustain a short shelf-life product network. The isotope is made on generators, with each generator only lasting approximately six months. Since most generators are manufactured outside of the US, they have potential exposure to tariffs. The fluorine-18 market for prostate-specific membrane antigen (PSMA) competes directly with the ^{18}F-FDG market for isotope sourcing, significantly impacting supply. These challenges with gallium-68 and fluorine-18 supply chains leave many cancer patients worldwide with limited access to radiodiagnostics and therefore affect their ability to receive timely, effective treatment.

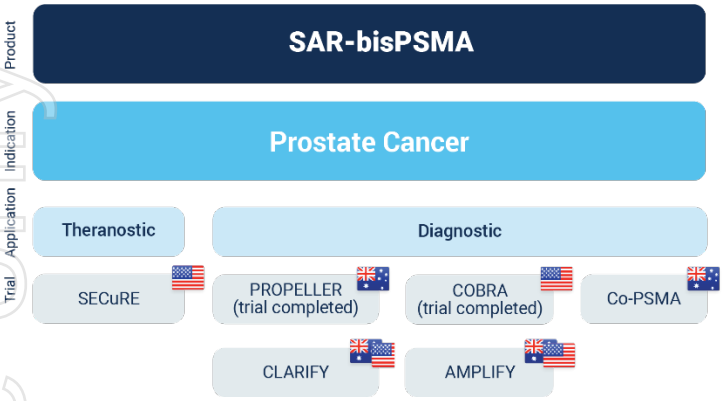
"The production and purification of copper-64 is an easy, proven, streamlined process developed over 30 years ago[3]. Utilising this process, SpectronRx has built the copper-64 production in-house for large-scale commercial markets. Broad, on-demand distribution, enabled by a shelf-life of up to 48 hours, combined with ease of central manufacture and the ability to produce up to 400,000 patient-ready ^{64}Cu-SAR-bisPSMA doses annually under one roof from SpectronRx's facility in Indiana, is a game-changer for the radiopharmaceutical field.

"We are already actively producing ^{64}Cu-SAR-bisPSMA for our clinical trials at SpectronRx. Given our positioning of this product as the next-generation PSMA diagnostic in the large market of prostate cancer, and our other imaging products generating exciting data and progressing through clinical development, the Commercial Supply Agreement considers options to expand manufacturing to similar sites in the US. By leveraging a proven, validated process and expanding to additional facilities, we can seamlessly move to larger commercial supply volumes to meet anticipated market demand. This option also allows us to fine-tune our commercial supply and distribution approach in the future as a multi-layered strategy, ensuring that we are able to fulfil the growing needs of clinicians and patients across the country on all levels: nationally, regionally and locally. We look forward to contributing to a change in the diagnostic paradigm for prostate cancer patients by providing a reliable, accessible and accurate diagnostic alternative to first-generation PSMA PET products."

This agreement builds on the Master Service Agreement and associated Supply Agreement for the copper-64 (Cu-64 or ^{64}Cu) isotope with SpectronRx, as well as the Clinical Manufacturing Agreement for the production of ^{64}Cu-SAR-bisPSMA for Clarity's Phase III trials, CLARIFY and AMPLIFY.

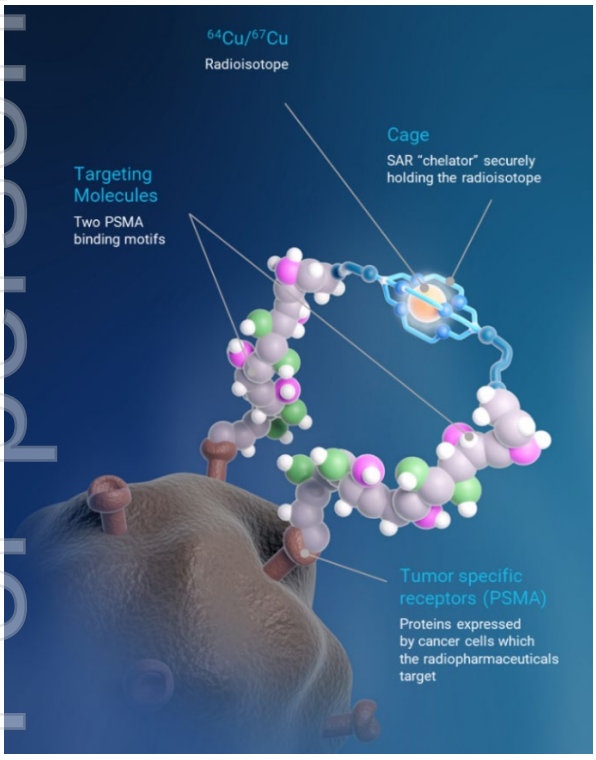
The Commercial Supply Agreement is effective as of 17 June 2025 and is for an initial period of five years. Cancellation and extension provisions are aligned with industry standard rates.

Overview of Clarity's SAR-bisPSMA clinical trial program



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 Targeted Copper Theranostic (TCT) that can be used with isotopes of copper-64 (Cu-64 or ^{64}Cu) for imaging and copper-67 (Cu-67 or ^{67}Cu) for therapy.



Disclaimer

^{67}Cu-SAR-bisPSMA and ^{64}Cu-SAR-bisPSMA are unregistered products. The safety and efficacy of ^{67}Cu-SAR-bisPSMA and ^{64}Cu-SAR-bisPSMA have not been assessed by health authorities such as the US FDA or the Therapeutic Goods Administration (TGA). There is no guarantee that these products will become commercially available.

About SpectronRx

SpectronRx is a diagnostic and therapeutic radiopharmaceutical developer and manufacturer with three distinct specialties: Radiopharmaceutical Contract Development (RCDMO), Radiopharmaceutical Contract Manufacturing (RCMO), and Isotope Production. The company performs all scales of development, from initial conjugations through scale-up and commercial distribution. It also has the capacity to run clinical trials. Additionally, SpectronRx's deep industry knowledge, technical prowess and state-of-the-art facilities enable the company to significantly condense the timeline for bringing new medicines to market, which has the dual benefit of saving lives and driving greater profitability for clients.

With a large staff of radiochemists, radiopharmacists, scientists and engineers, dozens of qualified clean rooms, and over 200,000 sq. ft. of production space in Indiana, with additional facilities in Danbury, Connecticut, and in Europe, SpectronRx now supplies therapeutic and diagnostic radiopharmaceuticals to 29 countries. The company has been EMA and FDA inspected and can produce and procure any currently used radioisotopes, including actinium-225. For more information visit SpectronRx.com, or follow the company on LinkedIn.

About Clarity Pharmaceuticals

Clarity is a clinical stage radiopharmaceutical company focused on the treatment of serious diseases. The Company is a leader in innovative radiopharmaceuticals, developing Targeted Copper Theranostics based on its SAR Technology Platform for the treatment of cancers.

www.claritypharmaceuticals.com

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