

ASX ANNOUNCEMENT

17 April 2025

Clarity signs high-volume commercial-scale copper-64 Supply Agreement with Nusano

Highlights

- Clarity has signed a commercial-scale agreement with Nusano, Inc. (“Nusano”) for supply of copper-64 (Cu-64 or ⁶⁴Cu) isotope.
- The 190,000 square foot Nusano facility in West Valley City, Utah is capable of producing more than 1,000 Ci (37,000 GBq) of copper-64 per day at capacity, which translates into more than 18,000 patient doses per day at 200 MBq per dose, with a 48-hour shelf-life, far in excess of commercial scale demands across multiple large indications.
- The copper-64 supply from Nusano will complement Clarity’s existing network of US-based suppliers to ensure seamless, abundant production of this diagnostic isotope as the Company is progressing a number of late-stage clinical trials and fast approaching commercialisation.
- Nusano plans to begin production of other medical isotopes, such as copper-67 and actinium-225, both of which are used in Clarity’s products, in 2025-2026.

Clarity Pharmaceuticals (ASX: CU6) (“Clarity” or “Company”), a clinical-stage radiopharmaceutical company with a mission to develop and commercialise next-generation products that improve treatment outcomes people with cancer, is pleased to announce the signing of a commercial-scale Supply Agreement for copper-64 with Nusano.

Nusano’s 190,000 square foot state-of-the-art facility in West Valley City, Utah is expected to begin production in 2025 with copper-64 isotope supply planned to commence in early 2026. The accelerator-based proprietary technologies employed by Nusano are particularly well suited for cost-effective mass production of copper-64. The Nusano facility is capable of producing more than 1,000 Ci (37,000 GBq) of copper-64 per day at capacity, which translates into more than 18,000 patient doses per day at 200 MBq per dose, with a 48-hour shelf-life, well in excess of commercial-scale demands across multiple large oncology indications in line with Clarity’s commercialisation strategy. Nusano is also developing in-house production of the target material for copper-64 manufacturing, nickel-64 (Ni-64), and plans to commence production of copper-67 (Cu-67 or ⁶⁷Cu) and actinium-225 (Ac-225 or ²²⁵Ac) isotopes in 2025-2026. Both of these isotopes are used in Clarity’s pipeline of theranostic products in development.

Clarity’s Executive Chairperson, Dr Alan Taylor, commented, “The signing of this Supply Agreement with Nusano will complement Clarity’s existing network of US-based copper-64 suppliers, providing capacity to ensure abundant and seamless supply of the isotope. As Clarity is generating exceptional data in a number of late-stage clinical trials, we now also have a cost-effective, large-scale supply strategy locked in for the commercial roll-out of our Targeted Copper Theranostics (TCTs) in the largest healthcare market in the world, the US. This Agreement is an important part of a larger commercial manufacturing strategy, which we will continue implementing as we get closer to the filing of New Drug Applications (NDA) with the US Food and Drug Administration (FDA).

“The ability to make isotopes and products in the US for the treatment of the American people is an important advantage in the current geo-political and economic environment. By building a supply chain that is fully

integrated, from high-volume isotope production, to centralised product manufacture, to delivering these ready-to-use diagnostics to imaging sites in every state of the US on time and on demand, we are aiming to build a model that is impervious to economic and political instability.

“In large oncology indications, such as prostate-specific membrane antigen (PSMA) positron emission tomography (PET) diagnostics (which Clarity is addressing with our key product, SAR-bisPSMA), ensuring stable, abundant and seamless supply of isotopes is crucial for a successful commercial launch.

“We have seen first-hand from the current generation of radio-diagnostics that efficient and timely product supply can make or break the adoption of the products and their expansion in the oncology practice. The current market leaders in PSMA PET imaging face several limitations associated with their short half-life (less than 2 hours vs. 12.7 hours for copper-64). These include short shelf-lives, restricted availability throughout the imaging site’s workday, and narrow imaging windows. At Clarity, our strategy is straightforward: we are determined to overcome these limitations and lay a strong foundation for the successful roll-out of TCTs globally.

“Our goal is to take radiopharmaceuticals to the next level by building a reliable and accessible supply that is consistent with the big pharma oncology model and deliver advantages to patients, their treating clinicians and imaging sites. Under this central manufacture model, the imaging sites will receive the copper-64 based diagnostics on demand, at any time and in volumes consistent with the rapidly growing demand of this blockbuster market. The clinicians have the added flexibility to administer the copper-based diagnostics and image patients over a significantly longer timeframe than what the current products allow. This translates into more flexibility for patient imaging and potentially higher lesion detection sensitivity that could lead to better identification of cancer lesions, helping to determine the best course of treatment for oncology patients.

“With our SAR-bisPSMA product generating a lot of exciting data and 3 US FDA Fast Track Designations granted for this product^{1,2,3} for accelerating its development, locking in commercial-scale supply of copper-64 means we are now closer than ever to changing the paradigm of prostate cancer diagnosis, ensuring no man is left waiting for a PSMA PET scan,” **said Dr Taylor.**

Nusano’s Chief Executive Officer, Chris Lowe, commented, “Nusano is commercialising a breakthrough radioisotope production platform in 2025 capable of producing more than 25 radioisotopes for life science applications, including copper-64, copper-67 and actinium-225. We are excited to enter into a Supply Agreement with Clarity for copper-64 to enable their clinical and commercial efforts with a dependable supply of radioisotopes from our world-class production facility in Utah.”

Additional Disclosure

The Supply Agreement is effective as of 16 April 2025 and is for an initial period of 3 years with automatic renewal for successive 2-year periods. Cancellation provisions are aligned with industry standard rates.

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

About Nusano

Nusano is a privately held physics company committed to bringing supply stability and innovation to the rapidly emerging and critically undersupplied medical radioisotopes market, and to serving industrial and commercial markets dependent on reliable access to high quality radioisotopes for their products and services. Driven by the company's proprietary ion source, the Nusano production platform will generate radioisotopes in volumes and varieties exceeding other production methods. Nusano's breakthrough technologies are poised to help supply the fight against cancer and enable innovation across multiple industries. For more, please visit [nusano.com](https://www.nusano.com).

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3. Clarity Pharmaceuticals. Clarity receives US FDA Fast Track Designation for the treatment of metastatic castration-resistant prostate cancer patients with Cu-67 SAR-bisPSMA. <https://www.claritypharmaceuticals.com/news/ftd-67cu-sarbispsma/>

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