ASX ANNOUNCEMENT

30 May 2024

Clarity strengthens Cu-64 network with new supply agreement with SpectronRx

Highlights

- Agreement with SpectronRx ensures seamless supply of the diagnostic copper-64 (Cu-64 or ^{64}Cu) isotope for Clarity's products which continue to progress through clinical trials, including a pivotal Phase III clinical trial.
- Cu-64 has an ideal 12.7-hour half-life that helps to overcome the overwhelming supply restraints of current-generation radiodiagnostics based on gallium-68 (Ga-68) with a half-life of ~1 hour and fluorine-18 (F-18) with a half-life of ~2 hours.
- Cu-64 is a new paradigm, enabled by Clarity's SAR Technology that specifically holds copper, allowing both the centralised, high-volume manufacture of diagnostic products and broad distribution to any location with a PET imaging camera.
- The optimal half-life of Cu-64 enables a larger imaging window from 1 hour to 30 hours after the patient receives the product, significantly reducing the scheduling strain on imaging centres as well as enhancing product performance with longer imaging timepoints.
- SpectronRx is a robust and established private supplier of Cu-64 that will support Clarity as it progresses towards a commercial launch of its Targeted Copper Theranostic (TCT) products.
- The agreement compliments and expands Clarity's existing network of Cu-64 suppliers across the US and Australia.

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 it has entered into a Supply Agreement with SpectronRx for the production of Cu-64.

Clarity's Executive Chairperson, Dr Alan Taylor, commented, "We are very excited to bring an additional Cu-64 manufacturer to our extensive and reliable network of copper radioisotope suppliers. SpectronRx will be the first private supplier of Cu-64 to join our network in the US.

"Cu-64, with an ideal 12.7-hour half-life, is able to overcome the overwhelming supply restraints of other diagnostic isotopes, specifically Ga-68 with a half-life of ~1 hour and F-18 with a half-life of ~2 hours. Radiopharmaceutical products using these isotopes are severely limited and are associated with significant manufacturing and supply complications, driven by these very short half-lives. This leaves many patients around the world with no option of positron emission tomography (PET) imaging. This is well documented in the United States, the largest oncology market in the world, and the effects of these hurdles more heavily impact vulnerable populations, including African Americans and Veterans, who already experience much higher incidences of prostate cancer than the general population[1, 2].

"Our focus at Clarity is to establish the most reliable, scalable, and logistically seamless supply chain in the radiopharmaceutical field to continue delivering our best-in-class products to patients and their clinicians on time. With our TCTs, we can avoid the myriad of challenges associated with the current generation of diagnostic isotopes, such as Ga-68 and F-18, which require local production due to their short half-lives.

"The unique properties of Cu-64 include the ability to produce commercially relevant volumes of this isotope daily, on centrally located cyclotrons. Cu-64 can then be manufactured into ready-to-use products with a shelf life that is measured in days rather than hours and supply the growing demand for PET imaging agents. Should an imaging site require 1, 10 or 100+ patient doses, we see a future where these quantities can be reliably supplied to any zip code in the United States, removing the burden of the current supply issues with Ga-68 and F-18 based products from

practices and their patients.

"We are now actively recruiting and imaging patients for our first Phase III trial with ^{64}Cu-SAR-bisPSMA in a pre-prostatectomy setting and planning our second Phase III trial in biochemically recurrent prostate cancer with this optimised product. With outstanding clinical trial data to date, we continue to implement our strategy for the commercial launch of ^{64}Cu-SAR-bisPSMA, developing a seamless supply chain for this potential best-in-class agent."

The overarching Master Service Agreement and associated Cu-64 supply agreement are effective as of 30 May 2024. The initial supply from SpectronRx is expected to launch before the end of calendar year 2024. The Master Services Agreement is for an initial period of five years and the Cu-64 supply agreement is for an initial period of 3 years. Cancellation and extension provisions are aligned with industry standard rates.

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 170,000 sq. ft. of production space in Indiana, with additional facilities in Danbury, Connecticut and 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 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

References

1. Cancer Stat Facts. National Cancer Institute Surveillance, Epidemiology, and End Results Program, https://seer.cancer.gov/statfacts/html/prost.html
2. Zhu K, Devesa SS, Wu H, Zahm SH, Jatoi I, Anderson WF, Peoples GE, Maxwell LG, Granger E, Potter JF, McGlynn KA. Cancer incidence in the U.S. military population: comparison with rates from the SEER program. Cancer Epidemiol Biomarkers Prev. 2009 Jun;18(6):1740-5. doi: 10.1158/1055-9965.EPI-09-0041. PMID: 19505907; PMCID: PMC2780333.

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