ASX ANNOUNCEMENT

8 October 2024

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

Highlights

- Clarity has entered into a ^{64}Cu-SAR-bisPSMA Clinical Manufacturing Agreement for its Phase III clinical trials with SpectronRx.
- This Clinical Manufacturing Agreement builds on the earlier Master Service Agreement and associated Supply Agreement for the copper-64 (Cu-64 or ^{64}Cu) isotope with SpectronRx, effective as of 30 May 2024.
- SpectronRx will produce both the ^{64}Cu isotope and the ^{64}Cu-SAR-bisPSMA product at the same facility in the US.
- As Clarity is progressing 2 registrational Phase III trials with ^{64}Cu-SAR-bisPSMA, this agreement ensures abundant and seamless supply with central distribution of the product from SpectronRx facility in Indiana to all 50 states on demand, providing universal access to this agent for the pivotal trials.

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 Clinical Manufacturing Agreement with SpectronRx for the production of the diagnostic ^{64}Cu-SAR-bisPSMA product for its Phase III trials. This agreement builds on the earlier Master Services Agreement and Supply Agreement for the production of the ^{64}Cu isotope, now allowing for a streamlined manufacturing process of both the isotope and the ^{64}Cu-SAR-bisPSMA product at the same facility.

SpectronRx's facility enables on-demand ^{64}Cu-SAR-bisPSMA manufacturing and distribution to all 50 states. This provides reliable, universal access of ^{64}Cu-SAR-bisPSMA in the U.S. for Clarity's Phase III trials, including the ongoing CLARIFY trial in the pre-prostatectomy setting, as well as the upcoming pivotal trial for prostate cancer patients with biochemical recurrence (BCR). The agreement with SpectronRx complements Clarity's existing supply network, providing a layered and abundant supply approach, which is unique in the radiopharmaceutical space.

Clarity's Executive Chairperson, Dr Alan Taylor, commented, "We are excited to continue strengthening our supply network, ensuring vulnerable patients in need of novel diagnostic options can get access to what we believe is a best-in-class product, on time and at any treatment centre with a positron emission tomography (PET) camera.

"Current-generation radiopharmaceutical diagnostic products rely on isotopes with very short half-lives, specifically Ga-68 with a half-life of ~1 hour and F-18 with a half-life of ~2 hours, which translate into short shelf-lives of the diagnostic products. This limits the use of these products to large treatment centres and hospitals with radiopharmacy facilities nearby that can produce F-18 and/or Ga-68. Cu-64 has an ideal 12.7-hour half-life and can overcome the overwhelming supply restraints of other diagnostic isotopes through central manufacture and distribution across the U.S. from a single facility. At Clarity, we believe that this approach has the potential to reduce disparities in prostate cancer care, providing patients with access to next-generation imaging products, regardless of their geographic location."

SpectronRx has a proven track record in generating multi-curie activities, representative of hundreds of patient doses, in a short irradiation window. SpectronRx also has in-house target preparation and integrated recycling facilities for Ni-64, the starting material for Cu-64 production. As such, the leftover Ni-64 after the initial production cycle can be recycled at SpectronRx. This avoids the inefficiencies, low yields and costs associated with the use of third-party systems for Ni-64 target production and target recycling that are more suited to small-scale on-site cold kit labelling.

"We look forward to swiftly progressing our Phase III trials with the assurance of abundant product supply and seamless distribution across the U.S. as we are getting closer to our ultimate goal of improving treatment outcomes for people with cancer," **Dr Taylor said**.

The Clinical Manufacturing Agreement is effective as of 8 October 2024 and is for an initial period of 24 months. 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

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