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ASIA EDITION

Australia's Clarity inks large-scale manufacturing supply agreement for copper-64 with Theragenics

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Theragenics has substantial cyclotron expertise with 40 years of routine radiometal production



Clarity Pharmaceuticals, an Australia-based clinical-stage radiopharmaceutical company with a mission to develop next-generation products that improve treatment outcomes for patients with cancer, has announced the signing of a large-scale Manufacturing Supply Agreement for copper-64 with US-based Theragenics.

The agreement relates to Theragenics' 134,000 square foot production facility with a fleet of 14 cyclotrons close to Atlanta, Georgia, a major US transport hub, for centralised, large-scale copper-64 (Cu-64 or ^{64}Cu) production ahead of anticipated ^{64}Cu-SAR-bisPSMA commercial launch upon successful completion of Clarity's Phase III registrational trials with this product, AMPLIFY and CLARIFY, and subsequent US Food and Drug Administration (FDA) New Drug Application (NDA) approval.

Theragenics has capacity to produce around 100Ci (3.7 TBq) of copper-64 per day on a single cyclotron, which translates into around 2,000 patient doses per day on each cyclotron at 200 MBq per dose with a 48-hour shelf life.

Together with Clarity's existing copper-64 supply agreements with SpectronRx and Nusano, this agreement with Theragenics further enhances Clarity's broad network of high-volume copper-64 manufacturers in distinct US geographies.

Mark Pugh, CEO of Theragenics, commented, "This agreement continues our expansion into the contract manufacturing organisation (CMO) isotope market, and we see Clarity as an ideal partner to advance this vision. Clarity is in a unique position with two diagnostic Phase III trials nearing completion, three Fast Track Designations (FTDs) from the US FDA and impressive data generated to date. With our core expertise and experience in producing radiometals for commercial medical purposes at Theragenics, together we can expand access to radiopharmaceuticals and bring a next-generation platform to patients in need of better diagnostics in the US."