

ASX ANNOUNCEMENT

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Clarity confirms no supply disruptions for its ongoing clinical trial programs

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, confirms Clarity's Targeted Copper Theranostic (TCT) products and clinical development programs using copper-67 (Cu-67 or ⁶⁷Cu) are unaffected by a recent shortage of actinium-225 (Ac-225) that has led to the delay in clinical trial recruitment¹⁻². Clarity also confirms that all of its Cu-67 suppliers are based in the United States, and the Company does not source any Cu-67 from Russia.

Clarity's Executive Chairperson, Dr Alan Taylor, commented, "There are still a number of challenges to be overcome to bring clinical and commercial stage Ac-225 production online, as well as other alpha radiopharmaceuticals such as lead-212 (Pb-212), while these isotopes continue to be relatively unproven in clinical trials. Clarity and all our current clinical development programs utilise Cu-67, which is produced domestically in the US on relatively low-cost electron accelerators, by our partners, including NorthStar Medical Radioisotopes, LLC.

"Clarity continues to source high purity and high specific activity Cu-67 for our three therapeutic programs with no interruptions and with capacity to support future pivotal trials and commercial launch. This is extremely important given the speed in which our clinical trials are recruiting and the exciting initial clinical signals from these programs. Our data with ⁶⁷Cu-SAR-bisPSMA is particularly exceptional as many patients have now experienced life changing outcomes from a single dose of the product and a patient with metastatic castration-resistant prostate cancer (mCRPC) achieved a complete response based on Response Evaluation Criteria in Solid Tumours (RECIST v1.1) assessment as well as a prostate-specific antigen (PSA) reduction to undetectable levels after just two 8GBq doses of ⁶⁷Cu-SAR-bisPSMA³.

"At Clarity, we have focused on building best-in-class products that are supported by reliable, dependable and environmentally friendly supply chains and manufacturing processes. We continue to build a sustainable future for radiopharmaceuticals as we progress our products through clinical trials in the US and Australia, with the ultimate goal of improving treatment outcomes for children and adults with cancer," Dr Taylor added.

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.

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References

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<https://endpts.com/rayzebio-warned-of-potential-isotope-supply-issues-before-bms-deal/>
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This announcement has been authorised for release by the Executive Chairperson.