

**ASX ANNOUNCEMENT**

16 July 2024

# Clarity signs supply agreement for Ac-225 with TerraPower Isotopes and launches Ac-225 bisPSMA program

**Highlights**

- Agreement signed with TerraPower Isotopes (TerraPower) for the supply of the therapeutic alpha-emitting isotope, actinium-225 (Ac-225 or <sup>225</sup>Ac), for Clarity's first Targeted Alpha-particle Therapy (TAT) program with bisPSMA.
- Clarity is now well positioned to develop a best-in-class TAT <sup>225</sup>Ac-bisPSMA product with secure supply combined with the increased uptake and retention of bisPSMA in tumours.
- TerraPower has a unique Ac-225 manufacturing process that has the potential to provide the scale and dependability needed for commercial manufacturing at a purity level appropriate for clinical use.
- Clarity will continue adding Ac-225 suppliers to its network as the manufacturing process continues to develop and progress to meet standards for clinical and commercial use.
- Clarity will continue to focus on <sup>67</sup>Cu-SAR-bisPSMA as its key program in PSMA-expressing prostate cancer because of the proven efficacy and robust safety profile of beta emitters affords an opportunity to target first line therapy, while <sup>225</sup>Ac-bisPSMA has potential to provide benefits to patients in later-stage disease.
- Developing both alpha- and beta-emitting therapies puts Clarity in a unique position to offer powerful treatment approaches to improve outcomes for prostate cancer patients.

**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 TerraPower for Ac-225 for Clarity's <sup>225</sup>Ac-bisPSMA program.

**Clarity's Executive Chairperson, Dr Alan Taylor, commented,** "We are very excited to explore the benefits of our proprietary optimised dual-targeted PSMA product in our first TAT program utilising TerraPower-supplied Ac-225. We have the right team to develop and later commercialise a best-in-class TAT product to complement the treatment paradigm, particularly in later-stage prostate cancer patients, and overcome the hurdles seen with other PSMA-based targeting agents.

"Manufacturing of Ac-225 poses a number of challenges at this time, including access for clinical studies, purity of isotope and scalability to meet requirements for a commercial launch. The Ac-225 from TerraPower fits into our strategy of developing sustainable, scalable and environmentally preferred solutions to radionuclide sourcing at a purity level appropriate for clinical practice and made directly in the United States. This avoids having to supply Ac-225 from Russia and use sources containing significant Ac-227 contamination, a radionuclide more radiotoxic than plutonium. A number of other isotope manufacturers are now developing potentially scalable commercial processes, including our existing partner for copper-67 supply, NorthStar Medical Isotopes LLC, and we will look to continue adding Ac-225 suppliers to our network. As such, with increasing focus on the Ac-225 supply chain, the probability of successfully developing and commercialising these treatments has grown from a supply perspective.

"The new beta-particle therapies, such as Cu-67 and Lu-177, with their favourable energy characteristics and path lengths, are revolutionising the radiopharmaceutical space because of their proven efficacy and excellent safety profiles compared to many other beta and alpha emitting isotopes. The small number of commercially available

targeted radiopharmaceutical therapies all use beta emitting isotopes, and they represent the best opportunity to significantly change the treatment paradigm with the potential for much earlier stage treatments and in combination with standard of care treatments or immuno-oncology products. Novartis, the current leader in radiopharmaceuticals, has cornered much of the Lu-177 supply market, given the precarious supply chain of Lu-177 and reliance on a limited number of aging nuclear reactors, inhibiting new companies from entering this space<sup>1</sup>. Clarity's unique proprietary position of having a cage that holds copper isotopes and exclusive supply of Cu-67, which is sourced from scalable electron accelerators as opposed to the small and aging fleet of nuclear reactors, means that Clarity is well positioned to drive a global shift in the treatment paradigm for cancer sufferers. As such, beta-particle therapy with Targeted Copper Theranostics (TCTs) remains Clarity's key focus.

"Clarity's bisPSMA program could be the game-changer in prostate cancer therapy given the increased uptake and retention in tumours enabled by the dual-targeting molecule and with impressive preclinical and clinical data generated to date. By combining our optimised bisPSMA with Ac-225, we have the opportunity to complement our beta-particle therapy product, <sup>67</sup>Cu-SAR-bisPSMA. Developing both alpha- and beta-emitting therapy products for prostate cancer puts Clarity in a unique position to offer powerful treatment approaches to improve outcomes for these patients as using each product at different stages of the disease would provide more options to the patients.

"Our <sup>225</sup>Ac-bisPSMA preclinical research program has been underway for some months with investigations to date focused on identifying a lead compound from a number of different analogues through measuring biodistribution, tumour uptake, radiolabelling efficiency and product stability as we move closer to clinical development with an optimised PSMA agent utilising Ac-225.

"By integrating TAT into our existing advanced TCT programs, Clarity is positioning itself to fundamentally transform the arsenal of treatments available for oncologists and their patients. This strategic move allows us to broaden our deep pipeline of clinical and pre-clinical assets and make significant progress towards our ultimate goal of better treating adults and children with cancer."

The Supply Agreement is effective July 2024. Supply under this agreement is expected to commence in November 2024, while supply before November 2024 will be carried out under the existing Limited Product Supply and Evaluation Agreement. The supply agreement is for an initial period of 2 years and can be extended under the terms of the contract. Cancellation provisions are at industry standard rates.

## About TerraPower

TerraPower Isotopes, LLC is a subsidiary of TerraPower, LLC. TerraPower Isotopes produced Actinium-225 is intended to be used as a starting material for further manufacturing process and, as a starting material is not manufactured in accordance with current good manufacturing practices.

TerraPower, LLC is a leading nuclear innovation company that strives to improve the world through nuclear energy and science. Since it was founded by Bill Gates and a group of like-minded visionaries, TerraPower, LLC has emerged as an incubator and developer of ideas and technologies that offer energy independence, environmental sustainability, medical advancement and other cutting-edge opportunities. It accepts and tackles some of the world's most difficult challenges. Behind each of its innovations and programs, TerraPower, LLC actively works to bring together the strengths and experiences of the world's public and private sectors to use advanced nuclear to answer pressing global needs. Learn more at <https://www.terrapower.com>.

## 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](http://www.claritypharmaceuticals.com)

## References

1. Brown, A. (2024, June 14). Radiopharma execs warn that lutetium could be at risk of shortage. *Endpoints News*. <https://endpts.com/radiopharma-exec-warn-that-lutetium-could-be-at-risk-of-shortage/>

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