

ASX MEDIA RELEASE

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Clarity's response to current media reports of shortages of reactor-produced medical isotopes

Clarity Pharmaceuticals (ASX: CU6) ("Clarity"), a clinical-stage radiopharmaceutical company developing next-generation products to address the growing needs in oncology, wishes to address recent enquiries made to the company and in the media^{1,2,3} regarding the outage at the High Flux Reactor (HFR) in Petten, Belgium.

On 24 January 2021, the Nuclear Medicine Europe (NMEu) Emergency Response Team (ERT) released a statement that the HFR did not resume operations after a planned shutdown on January 20, 2022, due to the detection of a water leak in the reactor beam tube cooling system.³ A further update from NMEu ERT on 31 January 2022 informed that the first planned cycle scheduled from 20 January until 20 February 2022 was subsequently cancelled and the reactor operator has stated the target date for restart cannot be provided⁴. The delay in the restart of the HFR reactor will impact the supply of such nuclear reactor produced medical radioisotopes as Mo-99/Tc-99m, Lu-177 and I-131.^{3,4}

Clarity's Executive Chairman, Dr Alan Taylor, commented, "Clarity does not source any of its copper isotopes from the limited number of aging nuclear reactors around the world that supply medical isotopes. We therefore do not foresee any impact of the HFR or other reactor outages on the manufacturing and supply of our Targeted Copper Theranostic (TCT) products now or anytime in the future. Our TCT platform employs electron accelerator produced Cu-67 and cyclotron produced Cu-64 radioisotopes, avoiding any of the issues faced by competing isotopes, such as Lu-177 and I-131, which rely on this aging fleet of nuclear reactors, the majority of which are located outside of the US⁵."

TCTs are the next-generation disruptive platform in radiopharmaceuticals that employ copper-64 (Cu-64) and copper-67 (Cu-67) for diagnosis and therapy respectively. Apart from delivering a compelling combination of high accuracy and high precision in the treatment of a range of cancers, TCTs provide supply and logistical advantages over current theranostics, including benefits in isotope production and supply.

Cu-67 is produced domestically in the US on electron accelerators with high purity and high specific activity for Clarity's therapeutic trials with Cu-67 SARTATE™ and Cu-67 SAR-bisPSMA. Cu-64 is produced on cyclotrons in the US and Australia for Clarity's diagnostic trials.

Dr Taylor said, "Radiopharmaceuticals are a small but extremely promising and fast-growing field in the very large oncology market, and it is predicted to grow strongly in the next 20 years as new products are developed and approved. The radiopharmaceutical industry is aware of the significant challenges of relying on a small number of aging nuclear reactors, whilst expanding the use of therapeutic radiopharmaceuticals from small and rare indications, such as the treatment of neuroendocrine tumours, to large indications, such as prostate cancer.^{2, 5, 6} If the industry continues to ignore this issue, it will have to face the prospect of further issues for the supply of radioisotopes, where closures of existing reactors as well as scheduled maintenance breaks and unplanned shutdowns, such as the ones we are experiencing with the HFR, are more common. These issues, coupled with the limited supply of precursor metals for the production of some reactor isotopes, may result in many patients unable to access these life-saving products.

"Clarity's TCT platform provides a robust solution as it is built around Cu-64 and Cu-67. The production of these radioisotopes is reliable, dependable, scalable and environmentally sustainable, with sufficient supply of precursor metals and no production of contaminants, providing confidence and certainty that the field can scale significantly and that critical treatments will be available to patients and their treating staff when and where they need it most. As such, Clarity looks forward to continuing to progress our clinical trials in pursuit of our ultimate goal of improving treatment outcomes for children and adults with cancer."

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

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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

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