

ASX MEDIA RELEASE

10 May 2022

Clarity confirms no supply issues to its ongoing clinical trials programs

Clarity Pharmaceuticals (ASX: CU6) ("Clarity"), a clinical-stage radiopharmaceutical company developing next-generation products to address the growing needs in oncology, confirms Clarity and its clinical development programs are unaffected by Novartis' recent suspension of production of Lutathera® and Pluvicto™/ ¹⁷⁷Lu-PSMA-617 at its facilities in Ivrea, Italy and Millburn, New Jersey.

On 5 May 2022, Novartis released an update regarding the suspension due to potential quality issues identified in its manufacturing processes and expects a resolution of these issues, and resumption of some supply, in the next 6 weeks. The production suspension impacts commercial and clinical trial supply as Novartis put a temporary hold on screening and enrollment for ¹⁷⁷Lu-PSMA-617 clinical trials globally, and Lutathera® clinical trials in the US and Canada.¹

Clarity's Executive Chairman, Dr Alan Taylor, commented, "Clarity and our clinical development programs are not impacted by the Novartis production disruption as our Targeted Copper Theranostics (TCTs) are wholly independent of the Lutathera® and Pluvicto™ supply chains and other first generation radiopharmaceuticals."

"Our greatest concern at this time is for the patients who need these important products now, and we hope that Novartis can re-commence supply shortly. As we have seen to date, the biggest threat to radiopharmaceuticals is not the efficacy of radiopharmaceutical products, but the ongoing sustainable supply of these products to patients. It has been known for many decades that radiation is a powerful weapon in the management and treatment of cancer; however, the lack of secure supply jeopardises market acceptance and confidence of clinicians and patients in these therapies," **Dr Taylor added.**

TCTs employ copper-64 (Cu-64) and copper-67 (Cu-67) for diagnosis and therapy respectively utilising proprietary SAR technology. TCTs are a next-generation disruptive platform in radiopharmaceuticals, which delivers a compelling combination of high accuracy and high precision in the treatment of a range of cancers, while providing supply and logistical advantages over current theranostics.

Cu-67 is produced domestically in the US on electron accelerators with high purity and high specific activity and Cu-64 is produced on cyclotrons around the world. Both isotopes have half-lives that favour centralised manufacture and broad distribution. The TCT platform also has a number of environmental benefits, including the clean production of isotopes without the creation of highly toxic and long-lived waste products during manufacture.

Utilising the many benefits of Clarity's SAR technology, all TCT products are manufactured at room temperature, significantly lowering the risk of batch failures, in contrast to first generation radiopharmaceuticals, including Lu-177 based products, which require heating the biological targeting agents to 90°C during manufacture. Furthermore, as the majority of nuclear reactors are located outside of the US², reactor-based radiopharmaceuticals also require long transit times into the US from other jurisdictions.

In recent times, a number of complications have arisen with nuclear reactor produced radiopharmaceuticals, most recently being the outage at the High Flux Reactor (HFR) in Petten, Netherlands, in February 2022^{3,4,5,6}. The EU has flagged this as a significant issue and advised that the European research reactors are approaching their "end-of-life". Without replacing this aging infrastructure, the EU could experience significant radioisotope shortages and impede access to vital treatments for its citizens. These shortages may impact the roll-out of lutetium-177 (¹⁷⁷Lu) based products, which will severely hinder the growth of radiopharmaceuticals moving forward.⁷

"Clarity's TCT platform of products aims to minimise all of these risks by clearly differentiating ourselves from the current pack of first generation radiopharmaceuticals and fully exploiting the many benefits of the "perfect pairing" of copper isotopes, including security and control of the entire supply chain, as we advance towards our ultimate goal of better treating children and adults with cancer," **Dr Taylor concluded.**

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

1. Novartis 2022, "Novartis provides update on production of radioligand therapy medicines", 5 May 2022, <<https://www.novartis.com/news/media-releases/novartis-provides-update-production-radioligand-therapy-medicines>>
2. Vogel et al 2021. Challenges and future options for the production of lutetium-177. EJNMMI 48, 2329-2335
3. Fischer, J.R. 2022, "Water leak in nuclear reactor expected to cause medical isotope shortage", 31 January 2022 <<https://www.dotmed.com/news/story/57018>>
4. Murphy, H. 2022, "Medical isotope shortage looms as 'unplanned' outage halts Mo-99, Lu-177 production", 26 January 2022, <<https://www.healthimaging.com/topics/molecular-imaging/isotope-shortage-reactor-halts-production>>
5. COMMUNICATION FROM THE NMEu EMERGENCY RESPONSE TEAM (ERT), "Unplanned Outage of the HFR Reactor", 24 January 2022, <<https://s3.amazonaws.com/rdcms-snmml/files/production/public/images/NMEU%20COMMUNICATION%2024%20JAN%202022%20Z.pdf>>
6. COMMUNICATION FROM THE NMEu EMERGENCY RESPONSE TEAM (ERT), "Update on Unplanned Outage of the HFR Reactor", 31 January 2022
7. Ligtoet, A., Scholten, C., Dave, A., King, R., Petrosova, L. and Chiti, A., Study on sustainable and resilient supply of medical radioisotopes in the EU, Goulart De Medeiros, M. and Joerger, A. editor(s), EUR 30690 EN, Publications Office of the European Union, Luxembourg, 2021, ISBN 978-92-76-37422-0, doi:10.2760/642561, JRC124565.