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Clarity confirms no supply interruptions 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, notes the recent supply interruption for Novartis' Pluvicto™ radiotherapy to patients[1-2] and confirms Clarity's Targeted Copper Theranostics (TCTs) products and clinical development programs are unaffected.

Clarity's Executive Chairman, Dr Alan Taylor, commented, "Clarity and our clinical development programs are not impacted by the Novartis supply disruptions as our TCTs are wholly independent of the Pluvicto™ supply chains and other current-generation radiopharmaceuticals. Radiopharmaceuticals offer novel and much needed treatments for oncology patients, which is supported by strong clinical data and a growing demand for these products; however, the key threat to the sector remains to be ongoing sustainable supply. The lack of seamless and secure supply jeopardises market acceptance and confidence of clinicians and patients in these treatments.

"Clarity's TCTs have the potential to resolve the ongoing supply issues as we differentiate ourselves from the pack of current-generation radiopharmaceuticals by employing copper-64 (Cu-64) and copper-67 (Cu-67) for diagnosis and therapy respectively. TCTs are a next-generation disruptive platform in radiopharmaceuticals, which delivers a compelling combination of high accuracy and high precision for the potential treatment of a range of cancers, while fully exploiting the many benefits of the "perfect pairing" of copper isotopes. This includes security and control of the entire supply chain, offering much needed reliability in the supply and manufacture of these products. We look forward to progressing our products through clinical trials in the US, including large indications such as prostate cancer, with the ultimate goal of improving treatment outcomes for children and adults with cancer."

Novartis has stopped accepting new patients and is rescheduling treatments for existing patients due to recent supply issues with the product.[1-2]

Pluvicto™ is a lutetium-177 (Lu-177) based radiopharmaceutical used to treat prostate-specific membrane antigen–positive metastatic castration-resistant prostate cancer (PSMA-positive mCRPC) and is also being investigated in additional PSMA-positive prostate cancer indications. It was approved by the US Food and Drug Administration (FDA) in March 2022 with peak sales projection of US$2 billion and reached sales of US$179 million just in the fourth quarter of 2022.[1] Despite the evident demand for the treatment and a significant unmet need in the prostate cancer indication, manufacturing and supply challenges remain a significant concern for the expansion of the drug in this large oncology indication.

Pluvicto™ is currently made in one manufacturing facility in Ivrea, Italy in small batches, with only a five-day window for each dose to reach its intended patient. Any interruption to this complex process can result in doses not arriving in time and the product expiring before it reaches the patient. In recent times, a number of such interruptions occurred, including a suspension of production of Lutathera® and Pluvicto™/ ^{177}Lu-PSMA-617 in May 2022 due to potential quality issues identified in its manufacturing processes[3] and a number of complications with nuclear reactor produced radiopharmaceuticals, such as the outage at the High Flux Reactor (HFR) in Petten, Netherlands, from January to March 2022[4-8]. These shortages may impact the roll-out of ^{177}Lu based products, which will severely hinder the growth of radiopharmaceuticals moving forward.[9]

Cu-67 is produced domestically in the US on relatively low-cost electron accelerators with high purity and high specific activity, unlike other therapeutic isotopes, such as Lu-177, which are produced on nuclear reactors, the majority of which are located outside of the US[10]. This enables shorter transit times in the US, allowing for additional flexibility with delivery and logistics of Cu-67 based therapies. Cu-64 is produced on cyclotrons around the world. Both Cu-64 and Cu-67 have half-lives that favour centralised manufacture and broad distribution of ready-to-use radiopharmaceuticals. 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.

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, some of which require heating the biological targeting agents to 90°C during manufacture.

"All of Clarity's seven clinical trials are currently recruiting, and there are no supply or manufacturing issues associated with our TCT programs. We look forward to building a sustainable and dependable future for radiopharmaceuticals as we progress towards our ultimate goal of better treating children and adults with cancer" Dr Taylor added.

About Prostate Cancer

Prostate cancer is the second most common cancer diagnosed in men globally and the fifth leading cause of cancer death worldwide[11]. The American Cancer Institute estimates in 2023 there will be 288,300 new cases of prostate cancer in the US and around 34,700 deaths from the disease[12].

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