ASX MEDIA RELEASE

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Clarity advances to cohort 3 of the CL04 trial of SARTATE™ in paediatric neuroblastoma

Highlights

- **Cohort 2 completed in participants with neuroblastoma who received therapy with ^{67}Cu SARTATE™ at a dose of 175MBq/kg body weight**
- **No Dose Limiting Toxicities (DLTs) have been reported in cohort 1 and cohort 2**
- **Safety Review Committee (SRC) has recommended the trial continues with the dose escalation phase as planned**
- **Recruitment of cohort 3 is open at all five clinical sites in the US at the increased dose level of 275MBq/kg body weight**
- **Additional therapy cycles of ^{67}Cu SARTATE™ have been requested by clinical sites and administered to participants in cohort 1 and cohort 2**
- **Additional clinical sites will be opening in the US in the coming months**

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 completed cohort 2 and advanced to cohort 3 in the theranostic ^{64}Cu/^{67}Cu SARTATE™ neuroblastoma trial (CL04 trial).

The independent Safety Review Committee (SRC) assessed the safety data from cohort 2 in all three participants, confirming no Dose Limiting Toxicities (DLTs) occurred following the administration of a single therapy cycle of ^{67}Cu-SARTATE. The SRC has recommended the trial progress to cohort 3, without modification, increasing the ^{67}Cu SARTATE™ dose from 175MBq/kg body weight in cohort 2 to 275MBq/kg body weight in cohort 3. Additional therapy cycles of ^{67}Cu SARTATE™ have been requested by clinical sites and are being administered to participants in cohorts 1 and 2. Subsequent therapy cycles are contingent on the Investigators assessment that the participant is demonstrating therapeutic benefit.

Clarity's Executive Chairman, Dr Alan Taylor, commented, "Our team of colleagues and collaborators are very excited to advance the SARTATE™ product in neuroblastoma, an aggressive childhood cancer. With cohort 2 of this theranostic trial now completed, we look forward to exploring the therapeutic benefits of using an increased dose of ^{67}Cu SARTATE™ in these children, where no other options are available. The further increase in dose between cohorts 2 and 3 is significant, and we look forward to analysing the safety and efficacy data in these higher-level cohorts in neuroblastoma, a radiation sensitive disease.

"We are also pleased with the speed of recruitment in cohort 2 and have been able to close this cohort in 6 months. The increased pace of recruitment is due to the subsided effects of the global pandemic. We continue to progress the trial at some of the leading cancer centres in the US and will aim to open additional clinical sites in the US over the coming months to further accelerate the speed of recruitment in this trial.

"Improving treatment outcomes of children with cancer is at the heart of our mission and something we are very passionate about. As such, we hope that Clarity will be able to continue building upon the mounting diagnostic and therapeutic benefits of the SARTATE™ products and improve the treatment paradigm for children with this insidious disease," **said Dr Taylor.**

About the CL04 trial

The CL04 trial is a Phase I/IIa theranostic (diagnosis and therapy) trial in paediatric patients with high-risk neuroblastoma using ^{64}Cu/^{67}Cu SARTATE™ in the US (NCT04023331)[1]. It is a multi-centre, dose-escalation, open label, non-randomised clinical trial with up to 34 patients currently conducted at five clinical sites in the US, with additional US clinical sites opening for recruitment in the coming months.

About SARTATE™

SARTATE™ is a next generation, highly targeted theranostic radiopharmaceutical. It is being developed for diagnosing, staging and subsequently treating cancers that express somatostatin receptor 2 (SSTR2), including neuroblastoma and neuroendocrine tumours (NETs). Like all Clarity products, the SARTATE™ product can be used with copper-64 (^{64}Cu) for imaging (^{64}Cu SARTATE™) or copper-67 (^{67}Cu) for therapy (^{67}Cu SARTATE™).

About Neuroblastoma

Neuroblastoma most often occurs in children younger than 5 years of age and presents when the tumour grows and causes symptoms. It is the most common type of cancer to be diagnosed in the first year of life and accounts for around 15% of paediatric cancer mortality.[2] High-risk neuroblastoma accounts for approximately 45% of all neuroblastoma cases. Patients with high-risk neuroblastoma have the lowest 5-year survival rates at 40%-50%.[3]

In 2020, the US Food and Drug Administration (FDA) awarded Clarity two Orphan Drug Designations (ODDs), one for ^{64}Cu SARTATE™ as a diagnostic agent for the clinical management of neuroblastoma and one for ^{67}Cu SARTATE™ as a therapy of neuroblastoma, as well as two Rare Paediatric Disease Designations (RPDDs) for these products. Should Clarity be successful in achieving marketing approval from US FDA for these two products, RPDDs may allow the Company to access a total of two tradeable Priority Review Vouchers (PRVs) which most recently traded at USD110M per voucher.[4]

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. ClinicalTrials.gov Identifier: NCT04839367 <https://clinicaltrials.gov/ct2/show/NCT04023331>
2. Nadja C. Colon and Dai H. Chung 2011, "Neuroblastoma", Advances in Pediatrics, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3668791>
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4. Fierce Biotech 14 July 2022, Marinus parts with priority review voucher, selling skip-the-line pass to Novo Nordisk for $110M, <https://www.fiercebiotech.com/biotech/marinus-parts-priority-review-voucher-selling-skip-line-pass-novo-nordisk-110m>

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