ASX MEDIA RELEASE

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Final cohort opens for recruitment in the CL04 theranostic trial in paediatric neuroblastoma

Highlights

- **Cohort 3 completed in participants with neuroblastoma who received therapy with ^{67}Cu SARTATE at a dose of 275MBq/kg body weight.**
- **Safety Review Committee (SRC) has recommended the trial continues with the dose escalation phase as planned.**
- **Recruitment of cohort 4 is open at clinical sites in the US at the increased dose level of 375MBq/kg body weight.**
- **Additional therapy cycles of ^{67}Cu SARTATE have been requested by clinical sites and administered to participants in the dose escalation to date.**

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 the successful completion of cohort 3 in the theranostic ^{64}Cu/^{67}Cu SARTATE neuroblastoma trial (CL04 NCT NCT04023331)[1]. Clarity is now progressing to the final cohort in the CL04 trial, where the highest dose in the dose escalation phase of the trial is administered.

The Safety Review Committee (SRC) assessed the safety data from cohort 3 in all three participants, and has recommended the trial progress to cohort 4, without modification, increasing the ^{67}Cu SARTATE dose from 275MBq/kg body weight in cohort 3 to 375MBq/kg body weight in cohort 4.

Some participants in the completed cohorts have received additional therapy cycles of ^{67}Cu SARTATE in addition to the single therapy cycle administered under the CL04 trial. These subsequent therapy cycles are strictly contingent on the investigators' assessment that the participant is demonstrating therapeutic benefit after the first dose.

Clarity's Executive Chairman, Dr Alan Taylor, commented, "We are excited to have reached this final cohort 4 in the CL04 trial. Neuroblastoma is one of the most aggressive childhood cancers and Clarity is dedicated to advancing the trial and exploring the diagnostic and therapeutic benefits of the SARTATE products in these affected children, where no other treatment options are available.

"The clinical and preclinical data to date is encouraging and we look forward to completing this final cohort and progressing to the next phase of the trial, cohort expansion. In the cohort expansion phase, we will enrol an additional 10 subjects who will receive at least 2 therapy cycles of ^{67}Cu SARTATE at the highest dose determined by the escalation phase, with up to 4 therapy cycles in total for those participants who demonstrate therapeutic benefit.

"We are excited to further advance the development of the SARTATE products and hope we can continue building upon their diagnostic and therapeutic benefits to improve treatment outcomes for children with this insidious disease." **said Dr Taylor**.

About CL04

The CL04 trial (NCT04023331)[1] 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. It is a multi-centre, dose-escalation, open label, non-randomised clinical trial with up to 34 patients currently conducted at eight clinical sites in the US.

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. Each year there are approximately 800 new cases registered in the US[2]. 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.[3] 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%.[4]

In 2020, the US 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 USD102M per voucher.[5]

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: NCT04023331, https://clinicaltrials.gov/ct2/show/NCT04023331
2. Cancer.Net Editorial Board, Neuroblastoma - Childhood: Statistics, https://www.cancer.net/cancer-types/neuroblastoma-childhood/statistics
3. Nadja C. Colon and Dai H. Chung 2011, "Neuroblastoma", Advances in Pediatrics, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3668791
4. Valeria Smith and Jennifer Foster 2018, "High Risk Neuroblastoma Treatment Review", Children, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6162495/
5. Sarepta Therapeutics Announces Sale of Priority Review Voucher for $102 million. 07/05/23. https://investorrelations.sarepta.com/news-releases/news-release-details/sarepta-therapeutics-announces-sale-priority-review-voucher-102

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