ASX MEDIA RELEASE

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First patient treated in cohort 2 SARTATE™ neuroblastoma therapy trial

Clarity Pharmaceuticals (ASX: CU6) ("Clarity"), a clinical-stage radiopharmaceutical company developing next-generation products to address the growing needs in oncology, is pleased to announce that it has successfully treated its first participant in cohort 2 of the $^{64}Cu/^{67}Cu$ SARTATE™ neuroblastoma therapy trial (CL04) at the increased dose level of 175MBq/kg body weight.

Clarity has recently progressed to cohort 2 of the CL04 trial following the completion of cohort 1 where three participants received therapy with ^{67}Cu SARTATE™ at a dose of 75MBq/kg body weight. The Safety Review Committee assessed the data from cohort 1 where no dose limiting toxicities have occurred and recommended to progress the trial to cohort 2, without modification, increasing the dose to 175MBq/kg body weight.

Clarity's Executive Chairman, Dr Alan Taylor, commented, "We are very excited to dose the first patient in cohort 2 in our neuroblastoma therapy trial in the US, having successfully completed cohort 1 in January 2022. The increase in administered activity between cohorts 1 and 2 is significant in radiation-sensitive disease, such as neuroblastoma, and cohort 2 will see administered activities more than double in comparison to cohort 1. We look forward to continuing recruitment in cohort 2 at all five clinical sites in the US, building upon the encouraging initial data from cohort 1 and further gathering evidence of diagnostic and therapeutic benefits of the SARTATE™ product for the treatment of children with neuroblastoma."

The CL04 trial is a theranostic (diagnosis and therapy) trial in paediatric patients with high-risk neuroblastoma (NCT04023331)[1]. It is a multi-centre, dose-escalation, open label, non-randomised, Phase 1/2a clinical trial with up to 34 participants conducted at five clinical sites in the US.

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 US FDA New Drug Applications for these two products, RPDDs may potentially allow the Company to access a total of two tradeable Priority Review Vouchers (PRVs) which most recently traded at USD110M per voucher.[4]

Dr Taylor said, "Our team, clinicians and collaborators have all shown strong dedication to progressing the neuroblastoma trial at some of the best cancer centres in the US, driven by our mutual goal of improving the treatment paradigm for children with this insidious disease. In the times when the pandemic was having a significant impact on clinical site operations and recruitment, this support is indicative of the importance and urgency of improving the prognosis of children with high-risk neuroblastoma, where current treatment strategies are limited. We continue working closely with the clinical sites and the US FDA to progress this trial swiftly, building upon the mounting evidence of the advantages of the SARTATE™ treatment paradigm over current treatment regiments, in pursuit of Clarity's 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

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>

3. Valeria Smith and Jennifer Foster 2018, "High Risk Neuroblastoma Treatment Review", Children, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6162495/>

4. BioSpace 17 November 2021, *Mirum Pharmaceuticals Sells Rare Pediatric Disease Priority Review Voucher*, <https://www.biospace.com/article/releases/mirum-pharmaceuticals-sells-rare-pediatric-disease-priority-review-voucher/>