ASX MEDIA RELEASE

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Clarity advances to cohort 2 in the SARTATE™ neuroblastoma trial

- **Cohort 1 completed in 3 participants with neuroblastoma who received therapy with ^{67}Cu SARTATE™ at a dose of 75MBq/kg body weight**
- **No dose limiting toxicities (DLTs) have been reported in cohort 1**
- **The Safety Review Committee (SRC) has recommended the trial continues with the dose escalation phase as planned**
- **Recruitment is open at all five clinical sites in the US at the increased cohort 2 dose level of 175MBq/kg body weight**
- **Additional therapy cycles of ^{67}Cu SARTATE™ have been requested by clinical sites and administered to patients in cohort 1**

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 completed cohort 1 and advanced to cohort 2 in the ^{64}Cu/^{67}Cu SARTATE™ Neuroblastoma trial (CL04 trial).

The SRC assessed the data from cohort 1 in three patients where no DLTs have occurred and recommended to progress the trial to cohort 2, without modification, increasing the dose from 75MBq/kg to 175MBq/kg body weight. Additional therapy cycles of ^{67}Cu SARTATE™ have been requested by clinical sites and are being administered to patients in cohort 1 in the CL04 trial. As part of the trial, patients have also received multiple doses of ^{64}Cu SARTATE™ for the imaging of tumours to assess disease localisation and eligibility for therapy. At the time of the SRC meeting, no adverse events had been reported relating to the administration of ^{64}Cu-SARTATE™.

Clarity's Executive Chairman, Dr Alan Taylor, commented, "We are very excited to successfully advance our SARTATE™ product in neuroblastoma, having completed cohort 1 of this therapy trial with ^{67}Cu SARTATE™. Dosing patients at 75MBq/kg body weight in cohort 1 of the CL04 trial enabled us to generate initial data to assess the safety profile along with some initial efficacy data for this product. We look forward to progressing the trial at some of the leading cancer centres in the U.S at the increased dose level of 175MBq/kg body weight, which we hope will build upon the mounting diagnostic and therapeutic benefits of this theranostic product and improve the treatment paradigm for children with this insidious disease."

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 patients 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, "The support and persistence we have experienced throughout the neuroblastoma trial to date from our numerous supporters, such as the clinical sites, Clarity's team, our collaborators and the US FDA, is indicative of the importance and urgency of improving the prognosis of children with high-risk neuroblastoma, where current treatment strategies are limited. Despite the challenges we faced during the pandemic, which had a significant impact on clinical

site operations and management, as well as recruitment hurdles in the US, we continue to progress this trial with increased determination and fervour to ensure we achieve our 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/>