ASX ANNOUNCEMENT

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First participant treated in the highest dose cohort of neuroblastoma trial

Highlights

- **First participant of cohort 4 of the theranostic CL04 trial investigating ^{64}Cu/^{67}Cu SARTATE in neuroblastoma has been treated at the highest dose cohort of 375MBq/kg body weight.**
- **Cohort 3 was successfully completed in 3 participants with neuroblastoma who received therapy with ^{67}Cu SARTATE at a dose of 275MBq/kg body weight.**
- **Additional therapy cycles of ^{67}Cu SARTATE have been requested by clinical sites and administered to participants in the dose escalation phase of the trial.**
- **NorthStar Medical Radioisotopes (NorthStar) supplied the ^{67}Cu that was used in the manufacturing of ^{67}Cu SARTATE for the dosing of the first patient in cohort 4.**

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 dosing of the first participant at the highest dose level of 375MBq/kg body weight in the final dose escalation cohort of the Phase I/IIa theranostic trial, CL04. No issues were observed during the administration of ^{67}Cu SARTATE and the participant continues to be followed for further safety and efficacy assessments as per protocol. The product administered to the participant was the first patient dose manufactured using copper-67 produced by NorthStar using their commercial scale manufacturing process.

The CL04 trial (NCT04023331)[1] is a theranostic trial evaluating ^{64}Cu/^{67}Cu SARTATE for diagnosis and treatment of high-risk neuroblastoma, an aggressive childhood cancer. It is a multi-centre, dose-escalation, open label, non-randomised, Phase I/IIa clinical trial with up to 34 participants conducted across eight clinical sites in the US.

Cohort 4 is the highest dose level cohort in the dose escalation phase of the CL04 trial. The aim of the dose escalation phase is to determine the optimal dose of ^{67}Cu SARTATE that can be safely administered. Once the optimal dose is established, the trial will progress to the dose expansion phase where an additional 10 participants will receive at least 2 administrations of ^{67}Cu SARTATE. Participants who demonstrate therapeutic benefit may be offered up to 4 therapy cycles of ^{67}Cu SARTATE in total.

Some participants in the earlier cohorts have received additional therapy cycles of ^{67}Cu SARTATE in addition to the single therapy cycle administered under the dose escalation phase of 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 Chairperson, Dr Alan Taylor, commented, "We are very excited to have dosed the first participant in this highest dose level cohort of our theranostic neuroblastoma trial in the US, having successfully completed cohort 3 very recently. We hope that the increase in administered activity between cohorts 3 and cohort 4 will have a significant impact on radiation-sensitive disease, such as neuroblastoma, and we look forward to generating the data from the 375MBq/kg body weight dose.

"High-risk neuroblastoma is a devastating cancer that predominantly affects children and has incredibly poor prognosis as there are few treatment options available to these patients with late-stage disease. At Clarity, we are dedicated to actively progressing the CL04 trial in the hope that our SARTATE product will deliver significant improvements to the diagnosis and treatment of children with this insidious disease in need of highly effective treatments.

The first ^{67}Cu SARTATE dose, administered in cohort 4 of the CL04 trial, was manufactured using copper-67 produced by NorthStar, the first commercial-scale supplier of this therapeutic radioisotope. NorthStar's copper-67 is manufactured using a scalable, efficient and environmentally preferable process based on electron accelerator technology. It has unique advantages compared to current-generation radiopharmaceuticals as they rely on aging nuclear reactors mainly outside the US.

NorthStar Medical Radioisotopes' President and Chief Executive Officer, Frank Scholz, Ph.D., commented, "We are very pleased and proud to be part of this important milestone, producing and supplying our first batch of Cu-67 for human use for the treatment of some of the most vulnerable patients, children with high-risk neuroblastoma. We are excited to be supporting Clarity's clinical development programs with copper-67 based therapeutic radiopharmaceuticals across their pipeline of Targeted Copper Theranostic products, with the mutual goal of improving treatment outcomes for children and adults with cancer."

Dr Taylor said, "We are pleased to be working with NorthStar as we develop next-generation theranostics with efficacious, scalable, sustainable and cost-effective supply chain that will enable the expansion of radiopharmaceuticals into the large, global oncology market."

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).

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).

^{64}Cu SARTATE and ^{67}Cu SARTATE are unregistered products. Individual results may not represent the overall safety and efficacy of the products. The data outlined in this announcement has not been assessed by health authorities such as the US Food and Drug Administration (FDA). A clinical development program is currently underway to assess the efficacy and safety of these products. There is no guarantee that these products will become commercially available.

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].

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

About NorthStar Medical Radioisotopes, LLC

NorthStar Medical Radioisotopes, of Beloit, Wisconsin USA, is a commercial-stage nuclear medicine company focused on advancing patient care by providing diagnostic and therapeutic radioisotopes, novel radiopharmaceuticals and customised radiopharmaceutical development services. Its proven management team and state-of-the-art, environmentally preferable and non-uranium based technologies have made it an emerging leader at the forefront of U.S. medical radioisotope and radiopharmaceutical production. NorthStar is expanding its industry-leading position in the growing area of therapeutic radioisotopes, used in targeted radiopharmaceutical therapy to treat cancer and other

serious diseases, and is poised to be the first commercial-scale producer of copper-67 (Cu-67).

For more information about NorthStar's comprehensive portfolio and patient-focused services, visit: *http://www.northstarnm.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/

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