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Recruitment successfully closes early for a diagnostic Phase II trial in neuroendocrine tumours

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 early recruitment closure for its Phase II diagnostic ^{64}Cu-SARTATE trial, DISCO (NCT04438304)[1], for patients with known or suspected neuroendocrine tumours (NETs). A total of 45 patients have been enrolled in the trial and all of the participants have now been administered and imaged with ^{64}Cu-SARTATE. All trial participants have now progressed to or have completed the follow-up stage.

The trial was originally planned for up to 63 patients based on an expected discordance level between imaging with Clarity's ^{64}Cu-SARTATE and the current standard of care, ^{68}Ga-DOTATATE. The sample size was adjusted to 45 patients based on the pre-planned assessment of the images to generate sufficient evidence to plan for a Phase III trial in this indication, enabling recruitment to successfully close early.

DISCO, which derives from "**D**iagnostic **I**maging **S**tudy of ^{64}**CO**pper-SARTATE Using PET on Patients with Known or Suspected Neuroendocrine Tumours", is assessing the performance of Clarity's SARTATE imaging product as a potential new way to help diagnose and manage NETs. The DISCO trial recruited participants with Gastroenteropancreatic NETs (GEP-NETs) across four sites in Australia, comparing the diagnostic performance of ^{64}Cu-SARTATE at 4 and 20 hours post-administration to ^{68}Ga-DOTATATE at one hour.

The trial aims to build on earlier work with SARTATE[2] which demonstrated that imaging at later time points, enabled by a longer half-life of ^{64}Cu in comparison to ^{68}Ga, may lead to better identification of disease.

Clarity's Executive Chairperson, Dr Alan Taylor, commented, "We are very pleased with the progress of our SARTATE product and the DISCO trial. Whilst the main focus for this product is on neuroblastoma in children, for both therapy and diagnosis, which includes two Rare Pediatric Disease Designations and two Orphan Drug Designations in this indication, the initial imaging data looks highly encouraging in NETs. We are optimistic the final trial results will underscore the diagnostic capability of ^{64}Cu-SARTATE for patients with NETs, and we eagerly anticipate the comprehensive analysis from the DISCO trial.

"Unfortunately, misdiagnosis and delays in diagnosis are prevalent in this patient population, but we believe that SARTATE has the potential to play a vital role in improving NETs diagnosis and treatment outcomes for these patients. We are confident the clinical advantages of SARTATE, combined with the logistical benefits of Targeted Copper Theranostics (TCTs), will ensure timely and convenient diagnosis and access to critical treatments for cancer patients.

"The Clarity TCT platform comprises of products not only focused on NETs, but also on other malignancies with high unmet need. Regarding our diagnostic portfolio, we were pleased to recently announce the recruitment closure of one of our studies in Gastrin Releasing Peptide Receptor (GRPR)-positive biochemically recurrent prostate cancer using SAR-Bombesin (SABRE, NCT05407311)[3,4] and the activation of the first site for our Phase III registrational study in pre-prostatectomy patients with SAR-bisPSMA (CLARIFY, NCT06056830)[5,6]. We are also eagerly awaiting to receive the data and initial analysis of the results from the COBRA study (biochemically recurrent prostate cancer using ^{64}Cu-SAR-bisPSMA, NCT05249127)[7] from our partnering contract research organisation, and at this stage we expect to share these results in early 2024".

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).

^{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 NETs

NETs, also known as well-differentiated neuroendocrine neoplasms or carcinoids, represent a heterogeneous group of malignant transformations of cells of the diffuse neuroendocrine system[8]. They most commonly occur in the gastrointestinal tract (48%), lung (25%), and pancreas (9%), but may also originate in other areas, including the breast, prostate, thymus and skin[9]. NETs can either be benign or malignant, as well as non-functional and functional[10]. NETs traditionally have been considered uncommon; however, the incidence has been increasing as a worldwide phenomenon[11]. This increase is thought to be mostly related to improvements in the way NETs are diagnosed, including better imaging tests and endoscopy, and increased awareness of these tumours[12].

Overall, it is estimated that more than 12,000 people in the United States are diagnosed with a NET each year, and approximately 175,000 people are living with this diagnosis[12]. Patients with GEP-NETs present with subtle clinical symptoms, which can lead to a delay in diagnosis of up to 5–7 years or result in inappropriate management[13]. As such, about 30-75% of NET patients have distant metastases at the time of diagnosis[14]. A 10-year relative survival rate for patients with metastatic GEP-NETs is 3–36%[15].

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

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