ASX ANNOUNCEMENT

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Positive guidance from the US FDA on Cu-64 SARTATE Phase III trial in patients with neuroendocrine tumours

Clarity Pharmaceuticals (ASX: CU6) ("Clarity" or "Company"), a clinical-stage radiopharmaceutical company with a mission to develop next-generation products that improve treatment outcomes for patients with cancer, is pleased to announce it will be commencing a pivotal Phase III registrational trial of its ^{64}Cu-SARTATE diagnostic agent in patients with neuroendocrine tumours (NETs). This follows a successful End of Phase meeting with the United States (US) Food and Drug Administration (FDA), in which all key components of the proposed trial design were agreed upon with the Agency. Recruitment into the trial is expected to commence in 2026.

The trial will be a multi-centre, single arm, non-randomised, open-label Phase III diagnostic clinical trial of ^{64}Cu-SARTATE Positron Emission Tomography (PET) in approximately 70 participants. As a pivotal trial, the final study results are intended to support an application to the US FDA for approval of ^{64}Cu-SARTATE as a new diagnostic imaging agent in NETs.

The aim of this registrational trial is to investigate the ability of ^{64}Cu-SARTATE PET/computed tomography (CT) to detect NETs, building on compelling preclinical and clinical trial data generated to date, including the first-in-human CL01 trial[1] and the Phase II DISCO trial (NCT04438304)[2-3]. The DISCO trial findings were recently accepted for presentation at the prestigious American Society of Clinical Oncology (ASCO) Gastrointestinal (GI) Cancers Symposium, which will be held January 8-10, 2026 (San Francisco, CA)[4].

In the DISCO trial, ^{64}Cu-SARTATE was found to be safe and well tolerated with lesion detection substantially higher than that of the current standard-of-care (SOC), ^{68}Ga-DOTATATE. ^{64}Cu-SARTATE also showed enhanced lesion detection in the liver, the most common metastatic site for patients with gastroenteropancreatic (GEP)-NETs. Hepatic metastatic burden is clinically important as it is strongly associated with patient outcomes and significantly influences clinical management of the disease[5]. The enhanced diagnostic capabilities of ^{64}Cu-SARTATE offer significant potential to transform and advance both the detection and management of patients with NETs, paving the way for improved patient outcomes and more effective treatment pathways.

Clarity's Executive Chairperson, Dr Alan Taylor, commented, "We are very excited to progress to a Phase III trial in the NETs indication and are thankful for the time and valuable guidance the FDA has provided on our ^{64}Cu-SARTATE agent during the End of Phase meeting. This will be our third registrational trial, highlighting Clarity's strong commitment to advancing our pipeline in areas of high unmet medical need with our next-generation Targeted Copper Theranostic products.

"Our team and collaborators are determined to progress ^{64}Cu-SARTATE through this registrational trial and towards commercialisation as we continue building on excellent preclinical and clinical data clearly illustrating the advantages of this product over SOC agents. Time and time again we have shown our commitment to the highest standards of scientific and clinical research, putting ourselves head-to-head against the current SOC to clearly emphasise the benefits and enhanced diagnostic performance of our products, something that very few radiopharmaceutical companies do.

"We would like to thank everyone who contributed to progressing ^{64}Cu-SARTATE to this exciting stage, from our patients who participate in our clinical trials and their families, to our incredible team, investigators and collaborators who work tirelessly towards our mutual goal of improving treatment outcomes for people with cancer. We also thank the FDA for their collaborative approach to our interactions, which we have now experienced for many years. We believe that better diagnostic tools will help clinicians determine the best course of treatment for their patients. With ^{64}Cu-SARTATE we are getting closer to achieving this goal, and we look forward to commencing recruitment into this pivotal trial next year."

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), such as 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).

Disclaimer

^{64}Cu-SARTATE is an unregistered product. The safety and efficacy of ^{64}Cu-SARTATE have not been assessed by health authorities such as the US FDA or the Therapeutic Goods Administration. There is no guarantee that this product 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[6]. 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[7]. NETs can either be benign or malignant, as well as non-functional and functional[8]. NETs traditionally have been considered uncommon; however, the incidence has been increasing as a worldwide phenomenon[9].

Overall, it is estimated that approximately 200,000 people are living with NETs in the US[10-11]. Patients with NETs present with subtle clinical symptoms, which can lead to a delay in diagnosis of more than 4 years[12]. As such, about 30-75% of NETs patients have distant metastases at the time of diagnosis[13]. A 10-year relative survival rate for patients with metastatic GEP-NETs is 3–36%[14].

About Clarity Pharmaceuticals

Clarity is a clinical stage radiopharmaceutical company focused on the treatment of serious diseases. The Company is a leader in innovative radiopharmaceuticals, developing Targeted Copper Theranostics based on its SAR Technology Platform for the treatment of cancers.

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