ASX ANNOUNCEMENT

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Clarity to present DISCO trial data at ASCO-GI 2026

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 the acceptance of an abstract and poster on the Phase II DISCO trial (NCT04438304)[1] data exploring ^{64}Cu-SARTATE in patients with known or suspected neuroendocrine tumours (NETs) to the prestigious American Society of Clinical Oncology (ASCO) Gastrointestinal (GI) Cancers Symposium 2026 held on the 8-10th January. The abstract is titled "Diagnostic performance of ^{64}Cu-SARTATE compared to ^{68}Ga-DOTATATE in patients with known or suspected neuroendocrine tumors with focus on liver findings".

The data to be presented builds on some of the previously announced results[2] that ^{64}Cu-SARTATE positron emission tomography (PET) / computed tomography (CT) lesion detection was substantially higher than that of the current standard-of-care (SOC), ^{68}Ga-DOTATATE PET/CT. ^{64}Cu-SARTATE was deemed safe and well tolerated. Out of 45 participants enrolled in the trial, only seven (15.6%) trial participants experienced a total of nine ^{64}Cu-SARTATE-related adverse events: eight were Grade 1 and one was Grade 2, with most resolving within 2 days.

The mean number of lesions detected by ^{64}Cu-SARTATE was approximately double that observed with ^{68}Ga-DOTATATE (441 vs. 227 lesions, respectively; averages across readers and both PET/CT timepoints for ^{64}Cu-SARTATE). Overall, a total of 238 discordant lesions (lesions that were only detected by one of the scans, either ^{64}Cu-SARTATE or ^{68}Ga-DOTATATE PET/CT) were identified in 34 subjects with scan pairs across all body regions, representing a large difference between detection abilities of the two agents. Of these discordant lesions, 223 were detected by ^{64}Cu-SARTATE alone and only 15 by ^{68}Ga-DOTATATE alone. Importantly, for the 122 discordant lesions with evaluable standard of truth ([SOT] biopsy and/or follow-up conventional imaging), the difference in sensitivity between the agents was highly significant, favouring ^{64}Cu-SARTATE (the sensitivities of ^{64}Cu-SARTATE vs. ^{68}Ga-DOTATATE were 94.7% [95% CI 65.1, 99.5] and 5.4% [95% CI 0.5, 34.9], respectively; $p<0.001$). This clearly demonstrates the considerable difference in sensitivity between ^{64}Cu-SARTATE and SOC imaging, based on lesions detected by either of the agents, showing that ^{64}Cu-SARTATE detected significantly more additional true-positive lesions compared to ^{68}Ga-DOTATATE in the same patients.

New data which is being presented at ASCO GI shows that the liver had the highest number of lesions detected by both tracers among all organs/regions assessed: ^{64}Cu-SARTATE PET/CT scans showed 352 lesions while ^{68}Ga-DOTATATE PET/CT only showed 180 lesions. The liver is the most common metastatic site for patients with gastroenteropancreatic (GEP)-NETs, and hepatic metastatic burden is clinically important as it is strongly associated with patient outcomes and significantly influences the clinical management of the disease[3]. Therefore, the enhanced diagnostic performance offered by ^{64}Cu-SARTATE, especially in key organs such as the liver, may allow clinicians to make treatment decisions with a greater degree of accuracy and confidence, with direct impact on patient outcomes. A Phase III study of ^{64}Cu-SARTATE is being planned.

Clarity's Executive Chairperson, Dr Alan Taylor, commented, "We are thrilled to continue generating valuable data, building further evidence of the best-in-class potential of our pipeline of products in development. As we are moving SARTATE towards commercialisation, it highlights our commitment to developing products for cancer indications with high unmet needs.

"Patients with NETs are often misdiagnosed and experience delays in receiving the correct diagnosis, which may lead to the identification of their cancer at later stages[4]. Visualising NET lesions earlier and more accurately at various stages of disease, especially in a critical organ like the liver, may have a significant impact on patient outcomes as it equips clinicians with crucial information on disease burden, helping to determine an optimal treatment plan.

"There are currently two key approved agents in the NETs PET imaging space, ^{68}Ga-DOTATATE and ^{64}Cu-DOTATATE, and both have substantial limitations when it comes to providing accurate and timely disease identification. These two products utilise the same chelator (i.e. cage), called DOTA, to hold diagnostic radioisotopes, while binding somatostatin receptor 2 (SSTR2), which is highly expressed in NETs. The key difference between the two agents is the isotope used to image patients, gallium-68 or copper-64. As we have seen with ^{68}Ga-DOTATATE in the DISCO trial, its sensitivity was very low among discordant lesions, meaning several lesions would go undetected until they grew larger in size, if at all. This limitation is primarily due to the short half-life of gallium-68 which underpins the requirement for imaging within 1 hour post-administration. We have seen first-hand that once radiopharmaceutical products are administered, they take time to find the lesion whilst also needing to clear from non-target organs, providing greater contrast, known as tumour-to-background ratio[5]. Having greater contrast is especially important to identify smaller or more difficult to find cancers. This is where the benefits of using copper-64 with its longer half-life play an important role. However, despite using copper-64, ^{64}Cu-DOTATATE has an important disadvantage where the DOTA chelator leaks copper *in vivo*[6]. Free copper-64 isotopes then accumulate in the liver, creating substantial background noise on PET scans which renders identification of lesions in the liver challenging. This is a key drawback with important clinical implications, as the presence of liver metastatic lesions is a notable prognostic factor in survival of these NET patients[3].

"^{64}Cu-SARTATE offers considerable advantages compared to approved SSRT2-targeted imaging agents, addressing some of their fundamental limitations and potentially providing patients and clinicians a chance to more accurately identify disease. As with all our products, we continue to rely on strong scientific foundations to develop ^{64}Cu-SARTATE, design its clinical trials and progress the agent towards commercialisation. While employing the same SSTR2 targeting molecule as the existing competitors, which have established safety and efficacy, we have circumvented the issue of copper leakage with the sarcophagine (SAR) cage, enabling optimal imaging timepoints. The proprietary SAR Technology, developed through outstanding Australian benchtop science from the Australian National University and the University of Melbourne, is able to securely hold copper, ensuring there is minimal background in the liver. The combination of optimal imaging timepoints, enabled by copper-64, and secure chelating of the isotopes, made possible by the SAR Technology, is what clearly differentiates ^{64}Cu-SARTATE from the competition, with the benefit of earlier and/or more accurate identification of lesions in NETs.

"With the improved diagnostic performance of ^{64}Cu-SARTATE, based on data generated to date, and the potential of improving treatment outcomes of patients with NETs through reliable and accurate disease identification, we are already planning a registrational Phase III trial of ^{64}Cu-SARTATE in NETs, aiming to expedite this unique agent to market."

About DISCO trial

DISCO is a "Diagnostic Imaging Study of ^{64}COpper-SARTATE Using PET on Patients with Known or Suspected Neuroendocrine Tumours". It assessed the performance of Clarity's SARTATE imaging product as a potential new method to diagnose and manage NETs. The trial aimed to build on earlier clinical experience with ^{64}Cu-SARTATE in patients with NETs, which demonstrated that the diagnostic has excellent imaging characteristics and suggested that ^{64}Cu-SARTATE PET/CT provides comparable or superior lesion detection to ^{68}Ga-DOTATATE PET/CT in all patients, especially in the liver[5].

DISCO recruited 45 participants with Gastroenteropancreatic NETs (GEP-NETs) across 4 sites in Australia, comparing the diagnostic performance of ^{64}Cu-SARTATE PET at an average of 4 hours (between 3 and 5 hours) and approximately 20 hours post-administration (same-day and next-day imaging, respectively) to the current SOC, ^{68}Ga-DOTATATE PET. Out of the 45, there were 41 participants with known NETs and 4 cases of suspected NETs. Most subjects had stage 3 or 4 disease.

Participants were required to have undergone a pre-study ^{68}Ga-DOTATATE PET/CT scan within 5 weeks, but not closer than 6 hours prior to the administration of ^{64}Cu-SARTATE as part of their routine clinical care.

About SARTATE

SARTATE is a next generation, highly targeted theranostic radiopharmaceutical. It is being developed for diagnosing, staging and subsequently treating cancers that express 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 Food and Drug Administration 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[7]. 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[8]. NETs can either be benign or malignant, as well as non-functional and functional[9]. NETs traditionally have been considered uncommon; however, the incidence has been increasing as a worldwide phenomenon[10].

Overall, it is estimated that more than 20,000 people in the United States are diagnosed with a NET each year[11], and approximately 190,000 people are living with this diagnosis[12]. Patients with NETs present with subtle clinical symptoms, which can lead to a delay in diagnosis of more than 4 years[13]. As such, about 30-75% of NETs 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 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.