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US-based Cu-64 SAR-bisPSMA trial in prostate cancer opens for recruitment

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 the diagnostic ^{64}Cu SAR-bisPSMA trial (COBRA NCT05249127[1]) for patients with prostate cancer is open for recruitment.

COBRA (**Co**pper-64 SAR-BisPSMA in **B**iochemically **R**ecurrent prost**A**te cancer) is a Phase I/II Positron Emission Tomography (PET) trial of participants with biochemical recurrence (BCR) of prostate cancer following definitive therapy. It is a multi-centre, single arm, non-randomised, open-label trial of ^{64}Cu-labelled SAR-bisPSMA in up to 50 participants. The primary objectives of the trial are to investigate safety and tolerability of ^{64}Cu-SAR-bisPSMA as well as its ability to correctly detect recurrence of prostate cancer.

Clarity's Executive Chairman, Dr Alan Taylor, commented, "We are excited to commence recruitment into the COBRA study with our first trial site, Urology Cancer Center and GU Research Network (GURN) in Omaha, Nebraska, actively recruiting patients just a few weeks after receiving the FDA Study May Proceed letter. The pace with which Clarity is able to open and progress the new trials of our optimised SAR-bisPSMA agent is indicative of the interest among the clinicians in the U.S. for this product and the benefits it could deliver to the patients and their treating staff."

Prostate cancer is a key focus of Clarity's Targeted Copper Theranostics (TCT) program where COBRA is one of the four clinical trials employing the SAR-bisPSMA agent. Most recently, Clarity announced a collaboration with GURN on a diagnostic ^{64}Cu SAR-bisPSMA investigator-initiated trial (IIT), X-Calibur (NCT05286840)[2], sponsored by Dr Luke Nordquist. The US-based theranostic ^{64}Cu/^{67}Cu SAR-bisPSMA trial, SECuRE (NCT04868604)[3], has been able to successfully image patients with metastatic castrate resistant prostate cancer from 1 hour to 72 hours post-injection. The diagnostic ^{64}Cu SAR-bisPSMA trial in Australia, PROPELLER (NCT04839367)[4], is well underway, with over 50% of participants recruited in untreated, confirmed prostate cancer patients (i.e. pre-radical prostatectomy). Clarity has previously received advice from the FDA that its prostate diagnostic clinical program with ^{64}Cu SAR-bisPSMA is addressing the two relevant patient populations for registration: pre-prostatectomy/pre-definitive treatment as well as patients with suspected biochemical recurrence.

Dr Neal Shore MD, FACS (CMO – Urology/Surgical Oncology, GenesisCare, US and the Medical Director of Carolina Urologic Research Centre), Lead Principal Investigator in the COBRA trial, commented, "We are very excited to initiate patient accrual for the COBRA trial which will explore and validate the clinical benefits associated with the novel SAR-bisPSMA agent. The preliminary data from Clarity's SECuRE and PROPELLER trials as well as preclinical data, indicate high uptake of Copper-64 SAR-bisPSMA, which suggests improved prostate cancer detection, inclusive of very low volume disease, which is especially important for patients with suspected disease recurrence. Importantly, the logistical advantages of central manufacture and the on-demand delivery of this novel imaging agent will provide enhanced accessibility to treatment facilities in the U.S. I look forward to expanding the trial U.S. sites and generating additional data for this next-generation technology which could ensure both ease of access and improved diagnostic accuracy for BCR patients."

Dr Taylor said, "Opening the recruitment into the COBRA trial is an exciting step in our prostate cancer program as it signifies the growing appetite for novel radiopharmaceutical treatments that can replicate the "big pharma" centralised manufacture model in the oncology field. TCT products can be delivered to clinical trial cancer patients and their treating staff on time and at a convenient location, with minimal delays and in sufficient quantities to meet the demand and address the backlog of patients waiting for these important diagnostic radiopharmaceuticals. We look forward to imaging prostate cancer patients in the COBRA trial and gathering further evidence of the clinical and logistical benefits of our optimised SAR-bisPSMA agent in pursuit of our ultimate goal of improving treatment outcomes for cancer patients."

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

For more information, please contact:

Clarity Pharmaceuticals
Dr Alan Taylor
Executive Chairman
ataylor@claritypharm.com

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 Prostate Cancer

Prostate cancer is the second most common cancer diagnosed in men globally and the fifth leading cause of cancer death worldwide[5]. The National Cancer Institute estimates in 2022 there will be 268,490 new cases of prostate cancer in the US and around 34,500 deaths from the disease[6].

References

1. ClinicalTrials.gov Identifier: NCT05249127 <https://clinicaltrials.gov/ct2/show/NCT05249127>

2. ClinicalTrials.gov Identifier: NCT05286840 <https://clinicaltrials.gov/ct2/show/NCT05286840>

3. ClinicalTrials.gov Identifier: NCT04868604 <https://clinicaltrials.gov/ct2/show/NCT04868604>

4. ClinicalTrials.gov Identifier: NCT04839367 <https://clinicaltrials.gov/ct2/show/NCT04839367>

5. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries <https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.21660>

6. American Cancer Society, Cancer Statistics Center, <https://cancerstatisticscenter.cancer.org/?_ga=2.79808020.284532473.1620009137-1916069442.1615761164#!/cancer-site/Prostate>