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New clinical trial collaboration for Cu-64 SAR-bisPSMA in prostate cancer

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 an investigator-initiated trial (IIT) will commence shortly in the US investigating ^{64}Cu SAR-bisPSMA in prostate cancer (NCT05286840)[1].

The X-Cancer's investigator-led trial of SAR-bisPSMA in known or suspected prostate cancer (X-Calibur) is a Phase I/II IIT in up to 150 patients at the Urology Cancer Center and GU Research Network (GURN) in Omaha, Nebraska, sponsored by Dr Luke Nordquist. It will investigate a broad spectrum of prostate cancer patients by imaging with ^{64}Cu-SAR-bisPSMA on the day of administration and at later timepoints. The X-Calibur trial will be assessing the safety of ^{64}Cu SAR-bisPSMA as well as looking at the impact of the product on staging and clinical management of participants with prostate cancer.

Clarity's Executive Chairman, Dr Alan Taylor, commented, "We are excited to support Dr Nordquist's trial, who has had first-hand experience with our products in the theranostic ^{64}Cu/^{67}Cu SAR-bisPSMA SECuRE trial (NCT04868604)[2]. We look forward to continuing to work together on progressing the development of our optimised SAR-bisPSMA agent in prostate cancer and exploring the many benefits of this product as part of Clarity's Targeted Copper Theranostics (TCT) program in pursuit of our ultimate goal of improving treatment outcomes for cancer patients."

Prostate cancer is a key focus of Clarity's Targeted Copper Theranostics (TCT) program, where the IIT at GURN is the fourth clinical trial utilising the SAR-bisPSMA agent in prostate cancer. The US-based theranostic ^{64}Cu/^{67}Cu SAR-bisPSMA trial, SECuRE (NCT04868604)[2], 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)[3], is well underway, with over 50% of participants recruited in untreated, confirmed prostate cancer patients (i.e. pre-radical prostatectomy). The most recent diagnostic ^{64}Cu SAR-bisPSMA trial in the US, COBRA (NCT05249127)[4], has received a Study May Proceed Letter from the FDA in February 2022, with recruitment of participants with biochemical recurrence of prostate cancer planned to commence in the second quarter of 2022. 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 Luke Nordquist, CEO and Urologic Medical Oncologist at the Urology Cancer Center and GU Research Network in Omaha, Nebraska, commented, "We are very impressed with the PET imaging data collected at GURN from the SECuRE trial which indicates high tumour targeting and retention, especially compared to first-generation PSMA agents that use a single PSMA binding motif and have very short half-lives of 1-2 hours. As such, we were excited to seize the opportunity and continue the development of SAR-bisPSMA in the diagnostic IIT at GURN, continuing to further expand the clinical benefits of the product and to provide our own prostate cancer patients with the very best technologies available.

"In addition to the clinical advantages, we have also been excited about the supply and logistical benefits of SAR-bisPSMA as a TCT, which can be distributed on-demand and in large scale from central manufacturing facilities. TCT can provide universal access to radiopharmaceuticals in every zip-code in the continental US, something that is lacking with current approved agents. GURN has a significant backlog of patients who cannot access sufficient quantities of PSMA imaging agents based on gallium-68 (Ga-68) or fluorine-18 (F-18) due to the logistical issues of short half-life isotopes. We have already experienced the benefits of Cu-64 based products and their longer shelf-life of up to 48 hours with our current trial with Clarity, and we expect minimal delays and interruptions as we look to address the large backlog of treatments, providing up to 150 prostate cancer patients with the critical imaging required to improve patient outcomes."

Dr Taylor said, "This fourth clinical trial of SAR-bisPSMA will build on the exciting data to date as we progress this product towards the market. The trial will also continue to demonstrate the numerous benefits of the centrally manufactured, on-demand distribution model of ready-to use cGMP TCT products over the first-generation short half-life products using Ga-68 and F-18. We look forward to Dr Nordquist advancing the X-Calibur trial and hope it will improve cancer diagnosis and ensure that critical treatments will be available to patients and their treating staff on time and at a convenient location when and where they need it most."

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

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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: NCT05286840 <https://clinicaltrials.gov/ct2/show/NCT05286840>

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

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

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

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>