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US FDA Study May Proceed letter for Clarity's ^{64}Cu SAR-bisPSMA trial 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 it has received a confirmation from the US Food and Drug Administration (FDA) that the diagnostic ^{64}Cu SAR-bisPSMA trial (COBRA) may proceed.

Clarity's Executive Chairman, Dr Alan Taylor, commented, "We are excited to be progressing this stand-alone diagnostic trial following a Study May Proceed letter from the US FDA as we head towards registering this product in the US. Following this exciting news, we are now planning to commence recruitment in the trial in the second quarter of CY2022."

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.

Prostate cancer is a key focus of Clarity's Targeted Copper Theranostics (TCT) program where COBRA is the third clinical trial of the optimised SAR-bisPSMA agent in prostate cancer. The US-based theranostic ^{64}Cu/^{67}Cu SAR-bisPSMA trial, SECuRE (NCT04868604)[1], has already demonstrated utility in patients with metastatic castrate resistant prostate cancer with imaging from 1 hour to 72 hours post-injection. The diagnostic ^{64}Cu SAR-bisPSMA trial in Australia, PROPELLER (NCT04839367)[2], is well underway, having reached its 50% recruitment milestone in untreated, confirmed prostate cancer patients (i.e. pre-radical prostatectomy) in December 2021. 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 Alan Taylor further commented, "The preliminary data from our SAR-bisPSMA trials in Australia and the US look very promising and the high uptake and retention of SAR-bisPSMA shown in preclinical and clinical trials to date may lead to improved detection in patients with prostate cancer, particularly those with low PSA levels. Our team and our collaborators are excited to commence the COBRA trial, generating more data to progress the development of SAR-bisPSMA as we move this product closer to registration in the US.

"We also look forward to further validating our on-demand distribution model as the trial sites will be supplied with ready-to-use cGMP ^{64}Cu-SAR-bisPSMA product. Clarity's vision is to move the diagnostic field towards centrally manufactured products that can be delivered on demand, shifting away from the supply constraints of the first generation of PET agents such as gallium-68 and fluorine-18 and the burdensome challenges of short-lived radionuclides. But most importantly, on-demand central manufacture of radiopharmaceuticals could potentially improve patient care by focusing on the needs of patients and their treating staff, delivering critical treatments that are safe and efficacious, on time and at any treatment centre with a PET camera."

Dr Neal Shore MD, FACS (CMO - Urology/Surgical Oncology, GenesisCare, US and the Medical Director of Carolina Urologic Research Centre), Principal Investigator in the COBRA trial, commented, "I am impressed by the images seen to date and look forward to working together with Clarity on the COBRA trial, exploring the clinical benefits of ^{64}Cu SAR-bisPSMA in patients with BCR of prostate cancer. Higher uptake of the product in tumours may offer improvements in diagnosis of disease, which is particularly relevant for patients with suspected recurrence of prostate cancer. The ability to diagnose the disease earlier offers the potential to provide better treatment options earlier. When these benefits are combined with the ability to supply the products on demand and in large scale, this may be a game changer for prostate cancer management."

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[3]. The National Cancer Institute estimates in 2021 there will be 248,530 new cases of prostate cancer in the US and around 34,130 deaths from the disease[4].

References

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

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

3. 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>

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