ASX ANNOUNCEMENT

4 July 2023

Positive guidance from US FDA on ^{64}Cu SAR-bisPSMA Phase III trial in prostate cancer

Highlights

- **FDA agreement for a pivotal Phase III trial for ^{64}Cu SAR-bisPSMA diagnostic in prostate cancer**
- **Phase III trial design based on ^{64}Cu SAR-bisPSMA data package, including positive results from the completed PROPELLER trial**
- **A total of 383 prostate cancer patients to take part in a pivotal, non-randomised, single-arm, open-label, multi-centre Phase III trial across multiple sites**
- **Trial expected to commence in late 2023**

Clarity Pharmaceuticals (ASX: CU6) ("Clarity", "the Company"), a clinical stage radiopharmaceutical company with a mission to develop next-generation products that improve treatment outcomes for children and adults with cancer, is pleased to announce it will be commencing a pivotal Phase III trial of its ^{64}Cu SAR-bisPSMA diagnostic in prostate cancer (PC) following a successful end of phase meeting with the US Food and Drug Administration (FDA). The trial will be named ***CLARIFY*** (*Positron Emission Tomography using ^{64}**C**u SAR-bisPSMA in participants with high-risk PC prior to radical prostatectomy: A prospective, sing**l**e-**ar**m, multi**-**centre, blinded-review, Phase III diagnostic per**f**ormance stud**y**)* and is expected to begin patient recruitment in late 2023.

The FDA is supportive of a prospective, non-randomised, single-arm, open-label, multi-center, Phase III diagnostic clinical trial of ^{64}Cu SAR-bisPSMA PET in 383 participants with untreated, histopathology-confirmed PC, with high-risk features, who are proceeding to radical prostatectomy with pelvic lymph node dissection. As a pivotal trial, the final study results are intended to provide sufficient evidence to support an application to the FDA for approval of ^{64}Cu SAR-bisPSMA as a new diagnostic imaging agent in PC.

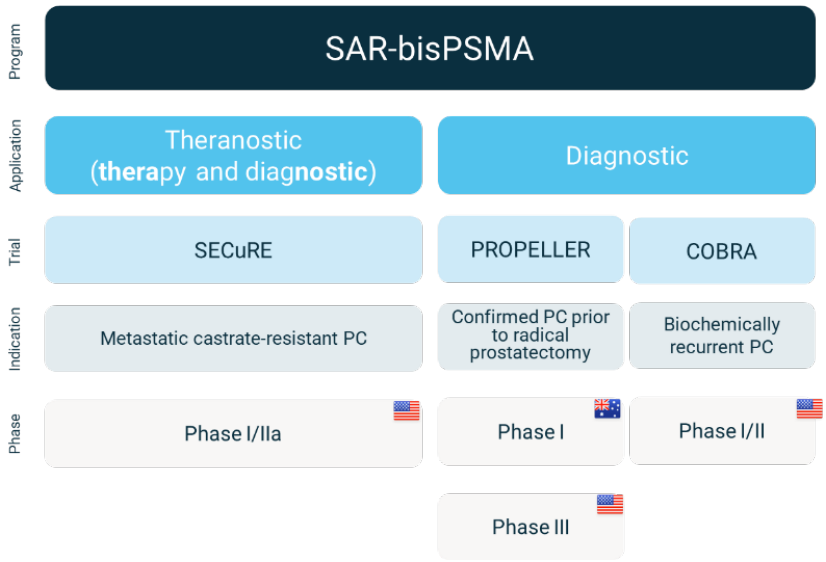
The aim of the Phase III trial is to assess the diagnostic performance of ^{64}Cu SAR-bisPSMA PET to detect PC within the pelvic lymph nodes. Evaluation will be across 2 imaging timepoints, Day 1 (day of administration) and Day 2 (approximately 24 hours post administration).

Clarity's Executive Chairperson, Dr Alan Taylor, commented, "We are very excited to progress our Phase III trial and are appreciative of the time and valuable guidance the FDA has provided in relation to our ^{64}Cu SAR-bisPSMA program during the end of phase meeting. The initiation of the CLARIFY trial is supported by compelling preclinical and clinical trial data. We would like to thank everyone who contributed to this exciting milestone, from our scientific collaborators at the University of Melbourne, who helped us overcome the low uptake and washout of first generation PSMA agents by assisting us in making an optimised PSMA agent for imaging and therapy, to the patients who participate in our clinical trials and to our incredible team and collaborators who work tirelessly towards our mutual goal of improving treatment outcomes for patients with PC. With this product, in both our diagnostic and therapy trials, we are now getting very close to achieving this goal.

"The positive results from our completed PROPELLER[1] trial showed that ^{64}Cu SAR-bisPSMA is safe, and its uptake in PSMA-expressing cancer lesions was significantly higher compared to the approved standard-of-care PSMA imaging agent for PC in Australia and the US. This may enable diagnosis of additional and smaller lesions, especially when coupled with the opportunity for delayed imaging, a characteristic not available to the first generation of PSMA imaging agents that exhibit high specificity but low sensitivity in diagnosing metastases outside of the prostate. Furthermore, we believe that the additional shelf-life of up to 48 hours could not only allow clinics greater flexibility in scheduling of the scans, but also improve patients' access to care in clinics and geographic areas where the short half-life of current PSMA PET tracers restricts the use of radiopharmaceuticals. We look forward to opening our Phase III trial later this year to confirm and build on the positive data we have seen on the ^{64}Cu SAR-bisPSMA product to date. Our hope is that better diagnostic tools will help clinicians determine the best course of treatment for their patients, informing a potential

life-changing decision between the surgical removal of the prostate and other treatment options that may support a better quality of life post-treatment. We are excited about further exploring these clinical benefits as well as the logistical and manufacturing advantages of our Targeted Copper Theranostics (TCTs) platform and bringing this next generation PSMA diagnostic to PC patients around the world."

Overview of Clarity's SAR-bisPSMA clinical trial program



About SAR-bisPSMA

SAR-bisPSMA derives its name from the word "bis", which reflects a novel approach of connecting two PSMA binding motifs to Clarity's proprietary sarcophagene (SAR) technology that securely holds copper isotopes inside a cage-like structure, called a chelator. Unlike other commercially available chelators, the SAR technology prevents copper leakage into the body. SAR-bisPSMA is a TCT that can be used with isotopes of copper-64 (Cu-64 or ^{64}Cu) for imaging and copper-67 (Cu-67 or ^{67}Cu) for therapy.

^{64}Cu SAR-bisPSMA and ^{67}Cu SAR-bisPSMA are investigational products and not yet approved by health authorities.

About Prostate Cancer

Prostate cancer is the second most common cancer diagnosed in men globally and the fifth leading cause of cancer death worldwide[2]. The American Cancer Institute estimates in 2023 there will be 288,300 new cases of PC in the US and around 34,700 deaths from the disease[3].

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 TCTs based on its SAR technology platform for the treatment of children and adults with cancer.

www.claritypharmaceuticals.com

References

1. ClinicalTrials.gov Identifier: NCT048393671, https://clinicaltrials.gov/ct2/show/NCT04839367
2. 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
3. American Cancer Society: Key Statistics for Prostate Cancer, https://www.cancer.org/cancer/prostate-cancer/about/key-statistics.html

For more information, please contact:

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

Catherine Strong
Investor/Media Relations
cstrong@citadelmagnus.com
+61 406 759 268

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