ASX ANNOUNCEMENT

18 November 2024

St Vincent's Hospital to conduct head-to-head trial with Clarity's SAR-bisPSMA diagnostic product

Clarity Pharmaceuticals (ASX: CU6) ("Clarity"), 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 a new Investigator-Initiated Trial (IIT), evaluating the performance of Clarity's diagnostic product, ^{64}Cu-SAR-bis-PSMA, in comparison to standard-of-care (SOC) ^{68}Ga-PSMA-11 product for the detection of prostate cancer recurrence.

The trial, named **Co-PSMA**, stands for "Comparative performance of ^{64}Copper [^{64}Cu]-SAR-bis-PSMA vs ^{68}Ga-PSMA-11 PET CT for the detection of prostate cancer recurrence in the setting of biochemical failure following radical prostatectomy". It is led by **Prof Louise Emmett** at St Vincent's Hospital, Sydney.

The Co-PSMA trial is a prospective, Phase II comparative imaging trial in 50 patients with biochemical recurrence (BCR) post-radical prostatectomy who are being considered for curative salvage radiotherapy. The primary objective of the study is to compare the detection rate of sites of prostate cancer recurrence, as determined by number of lesions per patient, between ^{64}Cu-SAR-bisPSMA and ^{68}Ga-PSMA-11 positron emission tomography (PET)/computed tomography (CT).

Prof Louise Emmett has been a member of Clarity's Scientific Advisory Board since 2022 and is deeply embedded in Australia's multidisciplinary clinical development and cancer research efforts. She is passionate about translational science, collaborating with biotechnology companies to bring promising theranostic agents into the clinic. Prof Emmett was Lead Principal Investigator in Clarity's successfully completed Phase I diagnostic ^{64}Cu-SAR-bisPSMA trial in patients with untreated prostate cancer, PROPELLER[1], which led to the registrational Phase III CLARIFY trial (NCT06056830)[2], currently recruiting patients in the U.S. and Australia. She also led 2 IITs with Clarity's SAR-Bombesin product in prostate and breast cancer indications, BOP[3] and C-BOBCAT[4] trials, respectively.

Dr Alan Taylor, Executive Chairperson of Clarity Pharmaceuticals, commented: "We are excited to deepen our collaboration with Prof Louise Emmett and St Vincent's Hospital, Sydney, through this new investigator-initiated Phase II trial. We pride ourselves on good Australian science and adhering to the highest standard for clinical research, so we look forward to working with Prof Emmett on generating data to highlight the benefits of our bisPSMA molecule over the current-generation diagnostics, such as the generic ^{68}Ga-PSMA-11. Through this IIT we also look to provide access to what we consider to be the best-in-class diagnostic to more men suffering from prostate cancer in Australia, and particularly in our home city of Sydney.

"The head-to-head comparison between ^{64}Cu-SAR-bisPSMA and ^{68}Ga-PSMA-11 PET presents a significant opportunity to continue demonstrating the superior diagnostic capabilities of our proprietary copper-based and bis-PSMA platforms. ^{64}Cu-SAR-bisPSMA's excellent performance has already been demonstrated in the COBRA trial[5], where we were able to image lesions more than 6 months prior to other standard of care imaging, identifying lesions with a diameter smaller than 2 millimetres. We know very well that early detection of cancer provides the best opportunities for better treatments, and this capability, coupled with the extended imaging window and logistical advantages, make it an ideal candidate to revolutionise care in these patients."

Prof Louise Emmett (St Vincent's Hospital Sydney), Principal Investigator in the Co-PSMA trial, commented: "Men with BCR after radical prostatectomy have a window of opportunity for a cure with the use of external beam radiotherapy. In order to achieve that, we need to use highly sensitive imaging techniques that can accurately detect the site of disease recurrence when the prostate-specific antigen (PSA) levels start to rise. This could really help improve patients' lives, and I am really looking forward to seeing whether the use of ^{64}Cu-SAR-bisPSMA has a significant management impact over the current standard ^{68}Ga-PSMA-11 PET CT, detecting sites of disease recurrence more accurately."

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

References

1. Lengyelova & Emmett et al. ^{64}Cu SAR bisPSMA (PROPELLER) Positron Emission Tomography (PET) Imaging in Patients with Confirmed Prostate Cancer. ASCO, 2023. https://www.claritypharmaceuticals.com/pipeline/scientific_presentations/
2. ClinicalTrials.gov Identifier: NCT06056830, https://clinicaltrials.gov/ct2/show/NCT06056830
3. Li & Emmett et al. Utility of ^{64}Cu-Sarcophagine-Bombesin PET/CT in Men with Biochemically Recurrent Prostate Cancer and Negative or Equivocal Findings on ^{68}Ga-PSMA-11 PET/CT. *J Nucl Med.* 2024 Sep 3;65(9):1371-1375. doi: 10.2967/jnumed.124.267881.
4. Wong & Emmett et al. ^{64}Cu-SAR-Bombesin PET-CT Imaging in the Staging of Estrogen/Progesterone Receptor Positive, HER2 Negative Metastatic Breast Cancer Patients: Safety, Dosimetry and Feasibility in a Phase I Trial. *Pharmaceuticals (Basel).* 2022 Jun 22;15(7):772. doi: 10.3390/ph15070772.
5. Nordquist et al. COBRA: Assessment of safety and efficacy of ^{64}Cu-SAR-bisPSMA in patients with biochemical recurrence of prostate cancer following definitive therapy. *ASCO*, 2024.

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