ASX ANNOUNCEMENT

26 October 2023

Clarity and PSI kick off SAR-bisPSMA Phase III

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, and PSI CRO AG ("PSI"), a global contract research organisation committed to on-time enrollment in radiopharmaceutical clinical trials, have entered into an agreement and have commenced work towards Clarity's Phase III diagnostic trial of SAR-bisPSMA in prostate cancer participants, CLARIFY (NCT06056830)[1].

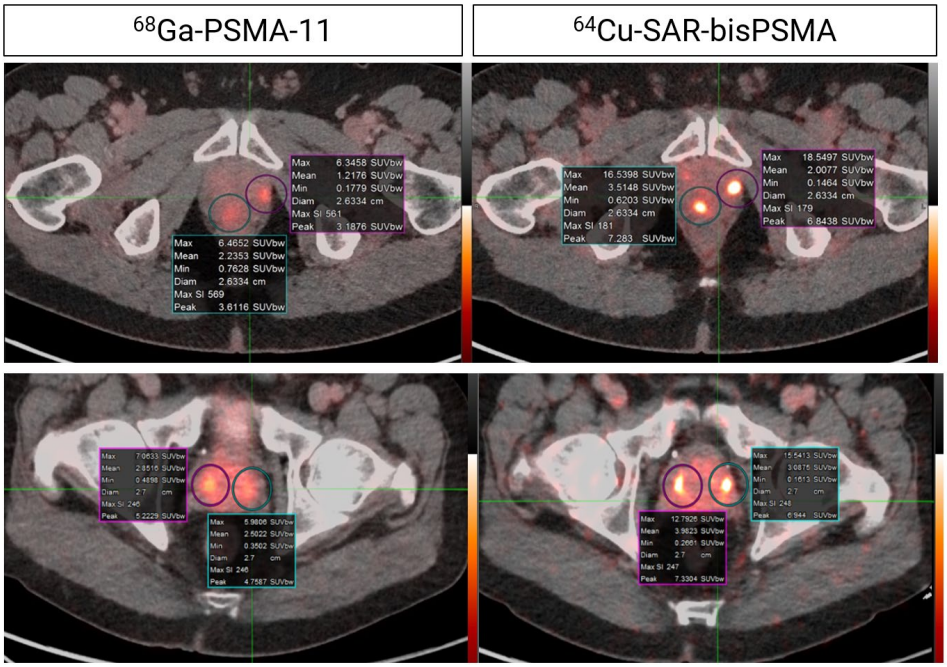
CLARIFY derives from "Positron Emission Tomography using ^{64}**C**u-SAR-bisPSMA in participants with high-risk prostate cancer prior to radical prostatectomy: A prospective, sing**l**e-**ar**m, mult**i**-centre, blinded-review, Phase III diagnostic per**f**ormance stud**y**". It is a non-randomised, open-label clinical trial in 383 participants.

The aim of the Phase III trial is to assess the diagnostic performance of ^{64}Cu-SAR-bisPSMA PET to detect prostate cancer within lymph nodes located in the pelvic region. Evaluation will take place over 2 imaging timepoints, Day 1 (day of administration) and Day 2 (approximately 24 hours post administration). CLARIFY is expected to begin recruitment in late 2023.

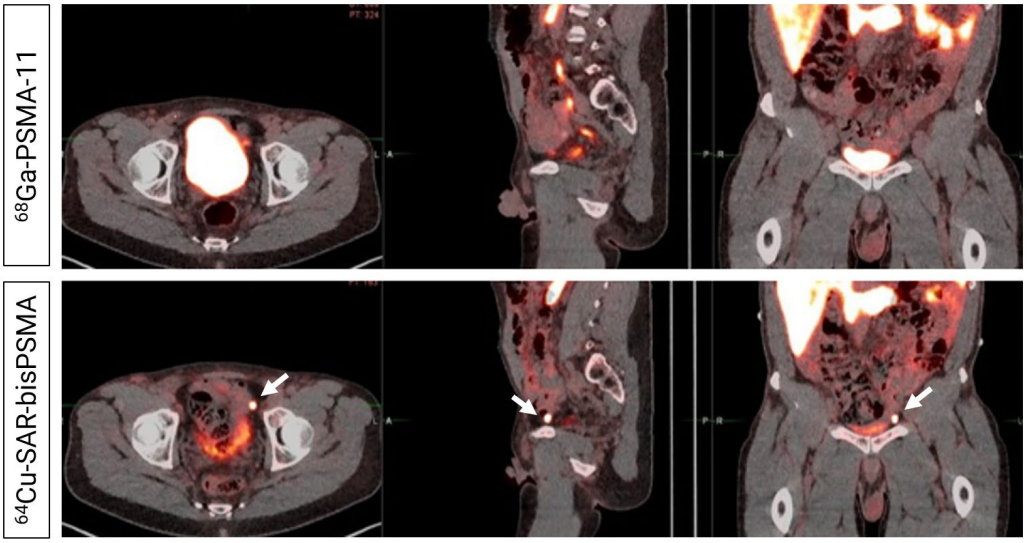
Clarity's Executive Chairperson, Dr Alan Taylor, commented, "We are very excited to move one step closer to initiating our first registrational Phase III trial. With recent positive and valuable guidance from the US FDA in relation to our ^{64}Cu-SAR-bisPSMA program, we look forward to commencing recruitment into the CLARIFY trial shortly and to gathering more data on this next-generation product to confirm the compelling preclinical and clinical trial results to date.

"The positive results from our completed PROPELLER[2] trial showed that ^{64}Cu-SAR-bisPSMA is safe and its uptake in PSMA-expressing cancer lesions was significantly higher compared to an approved standard-of-care PSMA imaging agent for prostate cancer in Australia and the US. This may enable diagnosis of additional and smaller lesions, which we observed in our PROPELLER[2] trial, and we are eager to investigate the further benefits of delayed imaging, particularly in this patient population, a characteristic not available to the first generation of PSMA diagnostic agents. Furthermore, we believe that the additional shelf-life of up to 48 hours will 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."

PSI's Senior Director of Operations, Rhonda Critchlow, commented, "Using our global database of over 400 radiopharmaceutical sites, we will be able to identify sites with the best resources and capabilities for the CLARIFY trial. We are excited to begin our collaboration with Clarity and will focus on the startup of high-performing sites to achieve the first patient in, in the shortest time possible. We believe that a myriad of clinical, logistical and manufacturing benefits of Clarity's Targeted Copper Theranostics platform holds promise of improving treatment outcomes for patients with cancer and look forward to working together on achieving this important goal."



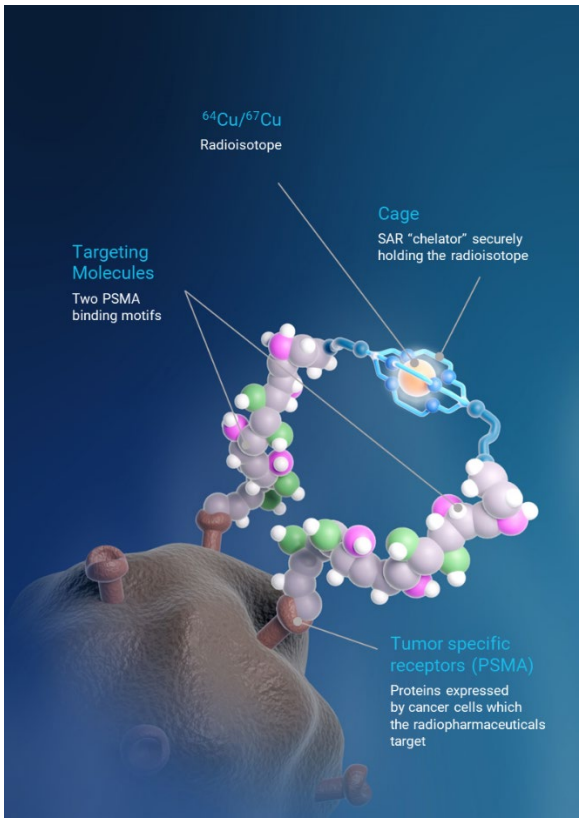
Concordant lesions on ^{64}Cu-SAR-bisPSMA (200 MBq) and ^{68}Ga-PSMA-11 PET/CT consistently showed higher SUVmax, SUVmean and tumor to background ratio with ^{64}Cu-SAR-bisPSMA compared to ^{68}Ga-PSMA-11. SUV: standardized uptake value. PROPELLER study.



Readers did not detect uptake in pelvic lymph nodes on the ^{68}Ga-PSMA-11 PET/CT (Top). PET/CT demonstrated uptake of ^{64}Cu-SAR-bisPSMA (Bottom) in a left pelvic lymph node according to both Readers. Prostate cancer was confirmed via histopathology. Arrows highlight the node detected on ^{64}Cu-SAR-bisPSMA PET/CT. PROPELLER study.

About SAR-bisPSMA

SAR-bisPSMA derives its name from the word "bis", which reflects a novel approach of connecting two PSMA-targeting agents to Clarity's proprietary sarcophagine (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 unregistered products. Individual results may not represent the overall safety and efficacy of the products. The data outlined in this announcement has not been assessed by health authorities such as the US Food and Drug Administration (FDA). A clinical development program is currently underway to assess the efficacy and safety of these products. There is no guarantee that these products will become commercially available.

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 American Cancer Institute estimates in 2023 there will be 288,300 new cases of prostate cancer in the US and around 34,700 deaths from the disease[4].

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 PSI CRO

PSI CRO is a privately-owned, full-service clinical research organization (CRO) operating globally. PSI's global reach supports clinical trials across multiple countries and continents and specialises in the planning and execution of global pivotal registration clinical trials. With an exceptionally high repeat and referral business rate combined with minimal staff turnover, PSI is committed to being the best CRO in the world as measured by its employees, customers, investigators, and vendors.

References

1. Positron Emission Tomography Using ^{64}Cu-SAR-bisPSMA in Participants With High-risk Prostate Cancer Prior to Radical Prostatectomy: A Prospective, Single-arm, Multi-center, Blinded-review, Phase 3 Diagnostic Performance Study – CLARIFY. ClinicalTrials.gov ID NCT06056830.
2. Lengyelova E, Wong V, Lenzo N, Parker M, Emmett L. ^{64}Cu-SAR-bisPSMA (PROPELLER) positron emission tomography (PET) imaging in patients with confirmed prostate cancer. ASCO 2023. Poster available at: claritypharmaceuticals.com/pipeline/scientific_presentations
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: Key Statistics for Prostate Cancer, https://www.cancer.org/cancer/prostate-cancer/about/key-statistics.html

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