ASX ANNOUNCEMENT

22 August 2024

Clarity receives FDA Fast Track Designation for ^{64}Cu-SAR-bisPSMA

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 that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for ^{64}Cu-SAR-bisPSMA for positron emission tomography (PET) imaging of prostate-specific membrane antigen (PSMA) positive prostate cancer lesions with suspected metastasis who are candidates for initial definitive therapy.

The FDA's Fast Track Designation is designed to expedite the development and regulatory review of novel drugs addressing serious conditions with significant unmet medical needs. For ^{64}Cu-SAR-bisPSMA, it provides a number of product development advantages. The designation paves the way for a potentially faster review process once Clarity submits its product approval application. Additionally, it enables more frequent communication with the FDA, allowing for rapid resolution of queries during development. Furthermore, Clarity can submit completed sections of its application as they are ready, rather than waiting for the entire package to be finished before it can be lodged with the FDA. These benefits would reduce the review time needed to bring this innovative prostate cancer imaging agent to market, potentially improving diagnosis and treatment planning for patients sooner.

Clarity's Executive Chairperson, Dr Alan Taylor, commented, "Receiving Fast Track Designation for ^{64}Cu-SAR-bisPSMA is a significant milestone, especially as we are actively recruiting into our first registrational Phase III trial, CLARIFY, and preparing for an End of Phase meeting with the FDA for a second pivotal Phase III trial with this product. The designation will allow us to work closely with the FDA to facilitate the development process, potentially accelerating the approval of this best-in-class diagnostic."

Clarity's ongoing clinical program with ^{64}Cu-SAR-bisPSMA includes trials in two indications: prostate cancer patients prior to undergoing radical prostatectomy, and with biochemical recurrence (BCR) of their disease. The completed Phase I PROPELLER study demonstrated favourable safety and efficacy results in patients with prostate cancer prior to radical prostatectomy. Driven by the compelling findings from the PROPELLER study, Clarity commenced a registrational Phase III trial in this patient population, CLARIFY, where recruitment is ongoing. In parallel, the Phase I/II trial, COBRA, ^{64}Cu-SAR-bisPSMA was found to be safe and highly effective in detecting prostate cancer lesions in patients with BCR. Based on the results from the COBRA study, Clarity commenced planning of a second registrational Phase III imaging trial. The Fast Track Designation is supported by the initial clinical evidence suggesting that ^{64}Cu-SAR-bisPSMA may offer improved lesion detection compared to existing prostate cancer diagnostics.

"We believe that ^{64}Cu-SAR-bisPSMA could be a game changer in prostate cancer diagnosis. Due to its dual targeting structure, bisPSMA, and the longer half-life of copper-64, enabling next-day imaging, this unique product has shown higher tumour uptake and retention and exhibited a capability of detecting much smaller lesions. The longer half-life of the isotope also translates into a longer shelf-life than currently used diagnostic radiopharmaceuticals, allowing for centralised manufacture and wider distribution, while also supporting flexible patient scheduling. These features are not available with gallium-68 and fluorine-18 based diagnostics. Clarity is committed to advancing the development of this best-in-class product to address the critical need for more accurate and accessible diagnostic tools in prostate cancer management.

"This designation highlights the potential of ^{64}Cu-SAR-bisPSMA to provide a novel diagnostic option for patients with prostate cancer and address the limitations of the current-generation diagnostic radiopharmaceuticals," **said Dr Taylor**.

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. The data outlined in this announcement has not been assessed by health authorities such as the U.S. 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 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.

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