ASX MEDIA RELEASE

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IND approval from the US FDA for theranostic SAR-Bombesin trial in prostate cancer

Highlights

- Clarity's fifth successful Investigational New Drug (IND) application with the United States Food and Drug Administration (US FDA), opening up therapeutic applications for SAR-Bombesin
- A total of six products with both the diagnostic and therapeutic applications for SARTATE, SAR-bisPSMA and SAR Bombesin are now under IND for US clinical trials
- First therapeutic clinical program for SAR-Bombesin will be in PSMA negative metastatic castrate resistant prostate cancer, an area of high unmet need

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, announces the approval of its Investigational New Drug (IND) application by the United States Food and Drug Administration (US FDA) to evaluate its SAR-Bombesin product for identification and treatment of metastatic castrate-resistant prostate cancer (mCRPC).

Clarity's Executive Chairman, Dr Alan Taylor, commented, "This trial with SAR-Bombesin marks our third therapy program, and sixth program overall, in the Targeted Copper Theranostic pipeline that is progressing through clinical trials in the US. Receiving clearance from the FDA is yet another significant milestone for the Company as it continues to showcase the capabilities of Clarity's small but high performing team in developing next-generation theranostics from the benchtop, through preclinical studies and into clinical trials in the largest pharmaceutical market in the world. This is Clarity's fifth IND, highlighting our strategy of developing radiopharmaceuticals for the very large US market."

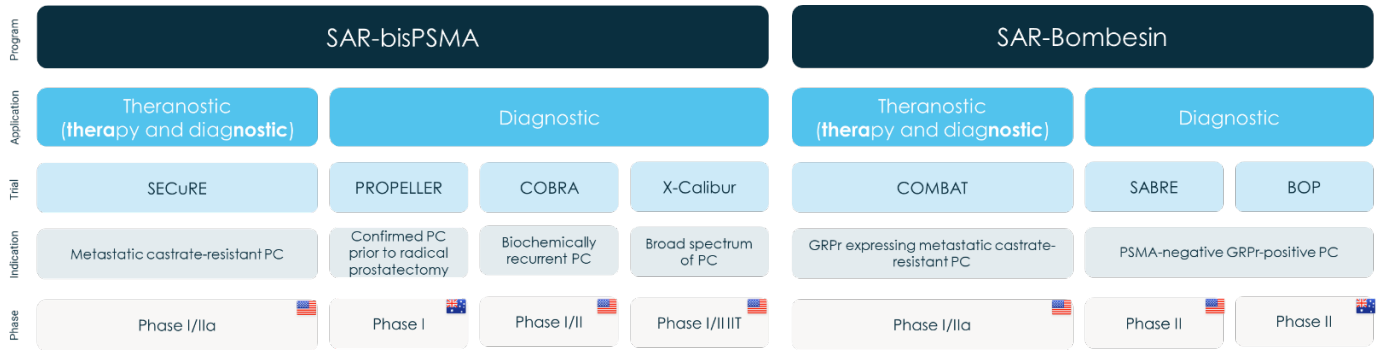
This IND gives Clarity clearance to proceed with a US-based Phase I/IIa ^{64}Cu/^{67}Cu SAR-Bombesin theranostic trial for identification and treatment of mCRPC that is expressing the Gastrin-Releasing Peptide receptor (GRPr).

COMBAT (**Co**pper-67 SAR Bo**mb**esin in metast**at**ic castrate resistant prostate cancer) is a dose escalation study with a cohort expansion. The aim for the study is to determine the safety and efficacy of ^{67}Cu-SAR-Bombesin in participants with GRPr-expressing mCRPC in patients who are ineligible for therapy with ^{177}Lu-PSMA-617.

Approximately 25% of mCRPC patients have low or no uptake of a PSMA-targeting tracer.[1] These patients are therefore unlikely to show uptake of PSMA-targeted products, such as ^{68}Ga-PSMA-11 for imaging or ^{177}Lu-PSMA-617 for therapy, and currently have few radiopharmaceutical treatment options available to them. Given prostate cancer is one of the largest indications in oncology, there is a significant unmet medical need in this segment. The SAR-Bombesin product targets the GRP receptor found on prostate and many other cancers. As such, the SAR-Bombesin could offer valuable imaging and therapeutic options for not only PSMA negative patients, but also the large number of patients that have the target receptor on their cancers.

Clarity's Executive Chairman, Dr Alan Taylor, commented, "We look forward to further progressing the development of SAR-Bombesin as a theranostic under this trial, as well as a stand-alone diagnostic agent under the SABRE and BOP clinical trials that are currently progressing in the US and Australia respectively. The diagnostic SAR-Bombesin product has already shown utility in improving the management of disease for PSMA-negative prostate cancer patients and, given the mounting clinical and preclinical data to date, we believe that it has potential to provide this large patient population with more accurate and precise detection and treatment of disease. SAR-Bombesin is a pan-cancer product, and the open IND offers exciting opportunities for exploring new theranostic indications with this versatile product as Clarity pursues our ultimate goal of improving treatment outcomes for children and adults with cancer."

Clarity's Prostate Cancer clinical trial program overview



About SAR-Bombesin

SAR-Bombesin is a highly targeted pan-cancer radiopharmaceutical with broad cancer application. It targets the gastrin-releasing peptide receptor (GRPr) present on cells of a range of cancers, including but not limited to prostate, breast and ovarian cancers. GRPr is found in approximately 75-100% of prostate cancers, including prostate cancers that don't express PSMA (PSMA-negative)[2-6]. The product utilises 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-Bombesin is a Targeted Copper Theranostic (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.

About Prostate Cancer

Prostate cancer is the second most common cancer diagnosed in men globally and the fifth leading cause of cancer death worldwide[7]. The National Cancer Institute estimates in 2022 there will be 268,490 new cases of prostate cancer in the US and around 34,500 deaths from the disease[8].

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. Vlachostergios PJ, Niaz MJ, Sun M, et al. Prostate-Specific Membrane Antigen Uptake and Survival in Metastatic Castration-Resistant Prostate Cancer. *Frontiers in oncology*. 2021;11.
2. Markwalder R, Reubi JC. Gastrin-releasing peptide receptors in the human prostate: relation to neoplastic transformation. Cancer research. 1999;59(5):1152-1159.
3. Fleischmann A, Waser B, Reubi JC. High expression of gastrin-releasing peptide receptors in the vascular bed of urinary tract cancers: promising candidates for vascular targeting applications. Endocrine-related cancer. 2009;16(2):623-633.
4. Ananias HJ, van den Heuvel MC, Helfrich W, de Jong IJ. Expression of the gastrin-releasing peptide receptor, the prostate stem cell antigen and the prostate-specific membrane antigen in lymph node and bone metastases of prostate cancer. The Prostate. 2009;69(10):1101-1108.
5. Reubi JC, Wenger S, Schmuckli-Maurer J, Schaer JC, Gugger M. Bombesin receptor subtypes in human cancers: detection with the universal radioligand (125)I-[D-TYR(6), beta-ALA(11), PHE(13), NLE(14)] bombesin(6-14). Clin Cancer Res. 2002;8(4):1139-1146.
6. Sun B, Halmos G, Schally AV, Wang X, Martinez M. Presence of receptors for bombesin/gastrin-releasing peptide and mRNA for three receptor subtypes in human prostate cancers. The Prostate. 2000;42(4):295-303.
7. 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>

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

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