

ASX MEDIA RELEASE

19 October 2021

## Recruitment on C-BOBCAT pilot cancer trial closed for Clarity's SAR-Bombesin product

- **C-BOBCAT breast cancer trial of Clarity's SAR-Bombesin product closes for recruitment.**
- **The diagnostic program with <sup>64</sup>Cu SAR-Bombesin generated evidence of the utility and potential superiority in some patient subgroups compared to conventional imaging (e.g. <sup>99m</sup>Tc bone scan, <sup>18</sup>F FDG).**
- **The high uptake and strong product retention visualised by PET imaging of patients at 1, 3 and 24 hours after product administration suggest significant potential for therapy applications with <sup>67</sup>Cu SAR-Bombesin.**
- **The human clinical data from the trial will be used for Investigational New Drug (IND) Application filings with the US Food and Drug Administration (FDA) with clinical trials for SAR-Bombesin in the US expected to commence in 2022.**

**Clarity Pharmaceuticals** (ASX: CU6) ("Clarity" or the "Company"), an Australian-based clinical stage radiopharmaceutical company developing next-generation products to address the growing need in oncology, is pleased to announce that the C-BOBCAT study led by Prof Louise Emmett has closed for recruitment at St Vincent's Hospital, Sydney.

C-BOBCAT is a pilot trial assessment of the diagnostic value of <sup>64</sup>Cu SAR-Bombesin PET/CT imaging for staging of ER/PR + HER2- breast cancer patients with metastatic disease in comparison with conventional imaging (CT, bone scan and <sup>18</sup>F FDG PET/CT). SAR-Bombesin has been used to image 7 patients with ER/PR positive metastatic breast cancer under the C-BOBCAT trial and a number of patients via the Therapeutic Goods Administration (TGA) Special Access Scheme (SAS) in both breast and prostate cancer patients.

**Clarity's Executive Chairman, Dr Alan Taylor, commented,** "We are very pleased with the imaging and safety data acquired during the trial and under the TGA SAS and have made a decision to close the trial early to enable the human clinical data to be used for regulatory submissions, including the upcoming Investigational New Drug (IND) Application filings with the US Food and Drug Administration (FDA) for SAR-Bombesin. As per our recent announcement, Evergreen Theragnostics, Inc. will be one of the US manufacturing groups to supply the Targeted Copper Theranostics for the US-based SAR-Bombesin clinical trial. We anticipate this trial to commence in 2022."

**Prof Louise Emmett, Principal Investigator in the C-BOBCAT trial at St Vincent's Hospital Sydney, commented,** "Our collaboration with Clarity on the C-BOBCAT trial has been a very exciting one as the diagnostic program with <sup>64</sup>Cu SAR-Bombesin generated evidence of the utility and superiority compared to conventional imaging in some patient subgroups (e.g. <sup>99m</sup>Tc bone scan, <sup>18</sup>F FDG). In addition to these benefits for some breast cancer patients, we also found SAR-Bombesin advantageous for prostate cancer patients who are prostate specific membrane antigen (PSMA) negative, thus validating the product's pan-cancer application. I look forward to finalising and publishing the results from the C-BOBCAT trial and wish Clarity every success in progressing this asset through clinical development."

**Dr Taylor said:** "SAR-Bombesin is a promising asset that can be developed for a number of cancer indications. The high uptake and strong product retention visualised by PET imaging of patients at 1, 3 and 24 hours after product administration suggest significant potential for therapy applications with <sup>67</sup>Cu SAR-Bombesin. We are excited to further advance its clinical development with a strong focus on regulatory approvals in the US and leverage the results generated in collaboration with some of the leading Australian scientific organisations and hospitals to reach our ultimate goal of improving treatment outcomes for children and adults with cancer."

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

**For more information, please contact:**

Dr Alan Taylor  
**Executive Chairman**  
[ataylor@claritypharm.com](mailto:ataylor@claritypharm.com)

Simon Hinsley  
**Investor/Media Relations**  
[simon@nwrcommunications.com.au](mailto:simon@nwrcommunications.com.au)  
+61 401 809 653

**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/](http://www.claritypharmaceuticals.com/)