ASX ANNOUNCEMENT

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Data on Clarity's SAR-bisFAP to be presented at the World Molecular Imaging Conference 2025

Clarity Pharmaceuticals (ASX: CU6) ("Clarity" or "Company"), a clinical-stage radiopharmaceutical company with a mission to develop next-generation products that improve treatment outcomes for patients with cancer, is pleased to announce that data on Clarity's pan-cancer theranostic, $^{64/67}$Cu-SAR-bisFAP, will be presented at the upcoming World Molecular Imaging Conference (WMIC) 2025 from the 29th September to October 3rd in Anchorage, Alaska by Dr. Michele De Franco, a research fellow at the Memorial Sloan Kettering Cancer Center (MSK) and Clarity's collaborator.

Clarity is developing $^{64/67}$Cu-SAR-bisFAP as potential pan-cancer theranostics targeting fibroblast activation protein (FAP), which is expressed on cancer associated fibroblasts (CAFs), a particular cell type found in the tumour microenvironment (cancer 'infrastructure' called the tumour stroma). FAP is found to be highly expressed in a broad range of cancers (e.g. breast, colorectal, pancreatic, lung, brain and ovarian cancers), but only minimally in normal tissue, making it a promising pan-cancer target for both imaging and treatment of cancers[1]. CAFs form part of the environment surrounding the cancer cells, and they can promote cancer growth and the spread of the tumour throughout the body[2]. Targeting the tumour stroma is an alternative way to treat cancer whereby the architecture of the tumour mass is targeted rather than the tumour cells directly.

As part of the optimisation process, Clarity developed and assessed two versions of the FAP-targeted product, one with a singular targeting molecule, SAR-FAP, and a dimeric version of the same molecule, SAR-bisFAP. Whilst both molecules have shown high tumour-specific uptake and targeting, the dual-targeting SAR-bisFAP has shown superior tumour targeting and retention in FAP-expressing mouse models (**Figure 1**).

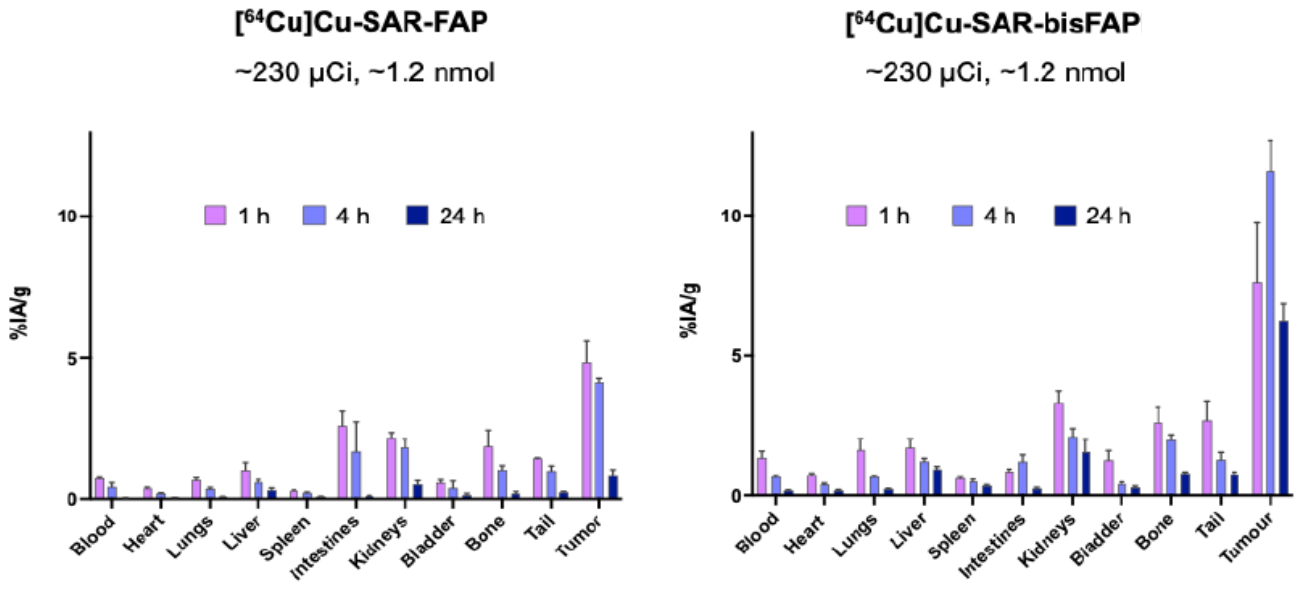

Figure 1. Comparison between the *ex vivo* biodistribution of ^{64}Cu-SAR-FAP and ^{64}Cu-SAR-bisFAP in FAP-positive U-87 MG (human glioblastoma) xenografts, showing how much product accumulated in each location, expressed as the percentage of the injected activity (%IA/g), at 1, 4, and 24 h post-injection.

Consistent with the enhanced tumour uptake observed using the dual-targeting ^{64}Cu-SAR-bisFAP, ^{67}Cu-SAR-bisFAP also showed improved efficacy in therapeutic mice studies, with a doubling in the median survival time of the mice who received 30 MBq of ^{67}Cu-SAR-bisFAP compared to those who received 30 MBq of the ^{67}Cu-SAR-FAP monomer or an industry benchmark, ^{177}Lu-FAP-2286 (median survival time was 28.5, 14.5, and 11.5 days, respectively).

Based on this data and results from previously completed pre-clinical studies, Clarity is aiming to progress the dual-targeting SAR-bisFAP theranostic products into human clinical studies, with a focus on the diagnostic in the first instance.

Dr Alan Taylor, Executive Chairperson of Clarity Pharmaceuticals, commented: "FAP-targeted products represent an exciting new generation of radiopharmaceuticals with the potential to target a range of cancer indications with high unmet needs. Consistent with our approach to high quality research and science, we continue to explore and optimise the most promising products in the field and going the extra mile to maximise their viability and success in the clinic. Starting from the benchtop, we work with thought leaders in the field to overcome the shortcomings of the existing products in development and generate strong data to support this. As a result of this commitment to excellence, we are now excited for our colleagues at MSK to share the results of the SAR-bisFAP products at one of the leading conferences in the field as they pave the way for clinical research in the near future.

"The diagnostic products using copper-64 and the therapeutics using copper-67 have shown high tumour targeting and retention in FAP-expressing xenograft mice models of cancer, with the dual-targeting ^{64}Cu-SAR-bisFAP showing improved retention compared to the monomer alone, and ^{67}Cu-SAR-bisFAP displaying improved efficacy compared to both ^{67}Cu-SAR-FAP and an industry benchmark, ^{177}Lu-FAP-2286. We believe these benefits are enabled by the optimised "bis" structure of our FAP product as well as the advantages offered by the perfect pairing of copper-64 and copper-67, securely held by our proprietary SAR chelator.

"Based on this data, we are currently conducting product development to enable a Phase I clinical trial in 2026 with ^{64}Cu-SAR-bisFAP, which will be followed by exploring potential treatment opportunities of cancers based on their unmet medical needs using ^{67}Cu-SAR-bisFAP in subsequent clinical trials."

About Clarity Pharmaceuticals

Clarity is a clinical stage radiopharmaceutical company focused on the treatment of serious diseases. The Company is a leader in innovative radiopharmaceuticals, developing Targeted Copper Theranostics based on its SAR Technology Platform for the treatment of cancers.

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References

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