

IMAGION BIOSYSTEMS LIMITED

ASX: IBX

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Imagion Closes Phase 1 Study – Announces Preliminary Performance of MagSense® HER2 Imaging Agent

Highlights

- Encouraging top-line performance of world's first molecular MRI test
- Pathology results from lymph node tissue shows concordance with MRI imaging

MELBOURNE — Imagion Biosystems Limited (ASX: IBX), a company dedicated to improving healthcare through the earlier detection of cancer, having successfully completed the MagSense® HER2 Imaging Agent Phase 1 study (IBI10103), is completing the closure of all clinical study-related activities throughout Australia with the final study site now taking no further enrolments.

In June, [the Company announced](#) that the study had achieved its enrolment target and recruited 13 patients. Emerging data was also disclosed with the Company announcing:

- Safety and tolerability - there have been no safety issues, toxicity or adverse events reported related to the imaging agent;
- Detectability - the MagSense® imaging agent is detectable by both imaging methods employed in the study, the Company's proprietary magnetic relaxometry technology and conventional Magnetic Resonance Imaging (MRI); and
- Potential Utility – the change in image contrast in nodes highly suspicious for tumour is distinctly different from the contrast seen in non-involved nodes.

Though this study was not designed or statistically powered to definitively characterize the performance of the MagSense® HER 2 Imaging Agent (MSH2IA), the Company is now pleased to announce the preliminary top-line performance of the world's first molecular MRI test.

Imagion's MSH2IA is designed to enable molecular MRI that detects lymph node metastatic HER2+ breast cancer in newly diagnosed patients. In the IBI10103 study, 13 patients were administered with the MagSense® HER 2 Imaging Agent. The drug was safe and well-tolerated, as there were no MSH2IA-related adverse events. 8 patients' MSH2IA molecular MRI results were interpretable by blinded radiologists participating in the study, as 3 subjects' tumour invasion impaired lymphatic drainage of the drug, and 2 subjects' MSH2IA molecular MRIs were marred by common MRI artifacts. Of the 8 interpretable patients, the actual pathology results from resected lymph node tissue agreed with the blinded radiologists' reports for 7 patients. Complete results will be released at December's San Antonio Breast Cancer Symposium and subsequently published, as previously announced.

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“The MagSense HER2 Imaging Agent Phase 1 clinical trial in Australia has been a tremendous success for the Company.”, said Dr. Isaac Bright, Imagion’s CEO. “The team’s ingenuity and diligence allowed us to deliver the world’s first molecular MRI contrast agent that may enable clinicians to non-invasively and accurately differentiate metastatic disease from benign lymph nodes in HER2-positive breast cancer patients.”

In the IBI10103 study, 13 HER2+ Breast Cancer patients were enrolled at 4 sites in Australia and treated with MagSense HER2 Imaging Agent to enable molecular MRI for detection of nodal metastasis of HER2+ Breast Cancer. The Company previously reported MSH2IA was safe and well-tolerated in June when it announced the IBI10103 study enrollment would close three of the four study sites as it did in July 2023. The Company is actively completing its first Investigational New Drug (IND) application, expecting submission to the US FDA in Q1 2024.

— ENDS —

About Imagion Biosystems

Established in 2017 and headquartered in San Diego, California, US, Imagion Biosystems is an ASX-listed company dedicated to developing innovative medical imaging technologies for various cancer types. Imagion Biosystems is advancing clinical development of its MagSense® platform technology to revolutionize cancer diagnosis, introducing molecular imaging to MRI. The Company’s lead program has demonstrated its innovative technology embodied in MagSense® HER2 Imaging Agent (MSH2IA) is safe and well-tolerated in patients diagnosed with HER2+ breast cancer. Imagion Biosystems’ MagSense® pipeline includes prostate cancer, ovarian cancer, pancreatic cancer, and brain cancer programs.

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Authorisation & Additional information

This announcement was authorised by the Disclosure Committee of Imagion Biosystems Limited.

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