Company Announcement

IMAGION BIOSYSTEMS LIMITED

ASX: IBX

7 December 2023

Imagion Announces Positive Results from IBI10103 Phase I Study Demonstrating Safety and Clinical Feasibility of Molecular MRI with MagSense® HER2 Imaging Agent

MELBOURNE and SAN DIEGO — Imagion Biosystems Limited (ASX: IBX) today announces positive results following completion of the IBI10103 phase I clinical trial evaluating the safety and clinical feasibility of MagSense® HER2 Imaging Agent (**MSH2IA**) as an adjunct to MRI for the assessment of axillary lymph node metastasis in patients diagnosed with HER2+ primary breast cancer. The trial met its endpoint of safety and tolerability, and showed that blinded radiologists may be able to distinguish suspicious lymph nodes that are infiltrated with metastatic HER2+ cancer from those involved in a healthy immune response or otherwise normally reactive. Thirteen women definitively diagnosed with HER2+ breast cancer were enrolled and treated with the drug without any safety issues, toxicity or drug-related adverse events reported.

Dr. Isaac Bright, Managing Director and CEO of Imagion, presented the data at the international San Antonio Breast Cancer Symposium today and said, “Patients with HER2 positive breast cancer need better staging options that are safe, reliable, comprehensive, and less invasive than today’s standard of care – axillary ultrasound and serial biopsy procedures. Too many of these women endure unnecessary interventions that provide incomplete information and impose unnecessary costs on global healthcare systems. We are encouraged by MSH2IA’s potential to increase the accuracy of disease staging, and thus improve treatment decisions.”

IBI10103 Phase I Study Results

The IBI10103 clinical trial was closed in October 2023 and evaluated the potential of the world’s first molecularly targeted MRI contrast agent, MSH2IA (MagSense® HER2 Imaging Agent), to enhance clinicians’ ability to non-invasively and more accurately determine the stage of HER2+ breast cancer. This trial, which was a multi-center open-label study, demonstrated the drug is safe and well-tolerated.

An international panel of blinded radiologists assessed pre-dose versus post-dose MRI scans of treated patients. 5 patients’ scans were not interpretable due to image artifacts or tumor invasion that precluded lymphatic drainage of MSH2IA to axillary lymph nodes. In a comprehensive assessment of the other 8 patients’ scans, the radiologists recognized MSH2IA uptake in both normal and malignant lymph nodes. Normal lymph nodes were recognized by a uniformly dark contrast

distributed throughout the entire node. Tumor-metastasized lymph nodes were observed to have heterogeneous scattered darkening. Importantly, MRI assessment of post-MSH2IA imaging achieved parity or outperformed standard-of-care axillary ultrasound imaging in all 8 of these patients. Molecular MRI with MSH2IA achieved nearly perfect patient-level concordance, as 7 of these 8 patients identified with tumor-metastasized lymph nodes post-MSH2IA MRI imaging were confirmed by post-surgical pathology analysis to have metastatic disease. The Company continues to work towards its Investigational New Drug application for submission to the US FDA, which was initially planned for Q1:2024, but now likely to be delayed as Imagion works to ensure sufficient resources are in place to pursue clinical development of the MagSense® imaging technology. As the global first-mover enabling molecular MRI, these results are very promising for Imagion and for improved precision oncology care. The Company is encouraged by the feedback IBI10103 results are attracting from prospective partners.

San Antonio Breast Cancer Symposium Poster

Dr. Bright today announced these findings in a premiere Spotlight poster presentation titled, *'Noninvasive Detection of Lymph Node Involvement in Subjects with Human Epidermal Growth Factor Receptor 2 Positive (HER2+) Breast Cancer using the MagSense® HER2 Test Reagent – A First-In-Human Phase I Study'* at the international San Antonio Breast Cancer Conference.

You can download a copy of the poster HERE >> https://info.imagionbio.com/sabcs-2023-poster-request

About HER2+ Breast Cancer

More than 2 million women worldwide are diagnosed with breast cancer annually, and approximately 20% of them are diagnosed with HER2+ breast cancer. Accurate disease staging is crucial, as treatment strategies vary based on primary tumor characteristics, lymph node status, and more distant metastatic disease. The current clinical standard of care for breast cancer staging relies on clinical assessment and diagnostic imaging. Axillary ultrasound for staging breast cancer is highly subjective and operator-dependent – as many as 50% of breast cancer patients may have their disease inaccurately staged. Inaccuracies at the outset of disease management leave a number of patients inadequately treated and subject others to wasteful and potentially harmful treatments and interventions. Molecular MRI with MSH2IA may emerge as the new standard of care for accurately staging the disease in patients diagnosed with HER2+ breast cancer.

About MagSense® HER2 Imaging Agent

The MagSense® HER2 Imaging Agent features a superparamagnetic iron oxide nanoparticle core synthesized at Imagion's GMP-compliant facility in San Diego, CA. It is coated with biocompatible polymers and functionalized with the monoclonal antibody trastuzumab or Herceptin®. MSH2IA is designed to be a single dose injected near the primary tumor and has been proven to drain through lymphatics, specifically targeting and binding to HER2+ breast cancer cells.

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About Imagion Biosystems

Established in 2017 and headquartered in the 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.

For more information, visit https://imagionbiosystems.com/investor-hub/

Imagion Biosystems Interactive Investor Hub

Engage with us directly by asking questions, watching video summaries, and seeing what other shareholders have to say about this and past announcements at our Investor Hub: https://investorhub.imagionbiosystems.com/

Authorisation & Additional information

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

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