Company Announcement

IMAGION BIOSYSTEMS LIMITED

(ASX: IBX)

19 February 2025

Imagion Initiates Manufacturing of MagSense® Drug for Phase 2 Clinical Study on HER2+ Breast Cancer

MELBOURNE – Imagion Biosystems (Company) (ASX : IBX), a company dedicated to improving healthcare outcomes through the early detection of cancer, is pleased to announce that it has initiated manufacturing of the MagSense® HER2 Imaging Agent, an essential requirement for filing an Investigational New Drug (IND) application with the US FDA in mid 2025.

The Phase 2 clinical study is a critical step in the development of the MagSense® HER2 Imaging Agent and the MagSense® imaging technology platform. A key milestone of basic safety was achieved with the successful completion of the Phase 1 study. For Phase 2 the Company aims to optimize the dose of the imaging agent and the imaging protocol to establish the diagnostic performance.

The Company is required to make the MagSense® Imaging Agent for human clinical investigational use in compliance with FDA guidance for Good Manufacturing Practices (GMP). The Company has previously made two batches of the imaging agent which were used in the Phase 1 study. This new batch of material will be used in the Phase 2 study that will be proposed to the FDA in the IND application. Based on the contract manufacturer's availability of the GMP suite, manufacturing to expected to commence in mid-April with production being completed in June.

"I'm very pleased that we have managed to get the manufacturing contract in place so quickly," said Bob Proulx, Executive Chairman. "*The receipt of funds from our recent capital raise has provided us with the resources needed to aggressively pursue our goal of filing an IND and preparing for the next phase of clinical testing of our novel imaging technology. With this key activity now in-process we are marching towards our next key development milestone*."

MagSense® HER2 Imaging Agent - Overview

The MagSense® HER2 Imaging Agent is intended to be used in the assessment of axillary nodal disease in patients diagnosed with HER2+ breast cancer. Precise nodal staging is an essential component in the management of patients with breast cancer. Currently, the most commonly employed method is ultrasound with pooled diagnostic sensitivity and specificity of 49% to 87%, and 55% to 97%, respectively. Since the HER2-positive subtype of breast cancer is considered an aggressive phenotype with a high rate of recurrence and metastasis, the development of a more sensitive and specific imaging method would be of significant clinical value for the more than 400,000 HER2 breast cancer patients diagnosed globally each year.

As previously disclosed, key tasks associated with meeting the IND milestone include:

i) **manufacturing a new batch of the MagSense® HER2 Imaging Agent;**
ii) **establishing the Principal Investigator to lead the study; and**
iii) **engaging with the Principal Investigator to finalize the study protocol in concert with FDA recommendations.**

With the production schedule from the contract manufacture now in hand the Company can establish a timeline for completing the additional key tasks and anticipates being able to file the IND 30-60 days after manufacturing has been completed.

This activity represents a use of funds consistent with prior disclosures. Whilst the Company has sufficient capital to proceed with the activities necessary to achieve filing of the IND, additional funding will be necessary to fund the Phase 2 study once approved by the FDA.

Authorisation & Additional Information

This announcement was authorised by the Board of Imagion Biosystems Limited.

— ENDS —

About Imagion Biosystems

Imagion Biosystems is developing a new non-radioactive and precision diagnostic molecular imaging technology. Combining biotechnology and nanotechnology, the Company aims to detect cancer and other diseases earlier and with higher specificity than is currently possible.

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

Media & Investor Relations:
Email: info@imagionbio.com
AU: +61 3 9692 7222