

IMAGION BIOSYSTEMS LIMITED

ASX: IBX

5 November 2025

Positive Results Received from WSU on MagSense® Dosage – Phase 2 Clinical Trial on HER2 Breast Cancer Imaging Agent

FDA Submission of IND for MagSense® HER2 Phase 2 Clinical Trial on Track Q4 2025

Key Highlights:

- **Wayne State University Collaboration Program Delivers Positive and Encouraging Results on HER2 Imaging Agent Dosages**
- **Important Milestone Met – WSU Program results will form part of Phase 2 Clinical Trial for IBX HER2 Breast Cancer Investigational New Drug (IND) Submission**
- **FDA submission of the MagSense® Imaging Agent HER2 Breast Cancer IND in Q4 2025 Remains on Schedule**
- **Final Steps of MagSense® Drug Product Manufacturing in Process**

Imagion Biosystems (ASX: IBX) (**Company or Imagion**), a company dedicated to improving healthcare outcomes through the early detection of cancer utilising its proprietary MagSense® imaging technology, is pleased to provide the markets with an update on progress towards the Company's planned Phase 2 study for HER2 Breast Cancer.

Positive Initial Results from Wayne State University on MagSense® Imaging Studies

The Wayne State University (WSU) collaboration, which focused on establishing the lower limits of detectability of the Company's proprietary MagSense® HER2 Imaging Agent to help establish the dose range for the planned Phase 2 study in HER 2 breast cancer patients and optimising imaging protocols for improved image quality, has yielded positive and encouraging results. This is a very important program with WSU, as the Company intends to use these results in support of its upcoming Investigational New Drug (IND) application to be submitted with the U.S. Food and Drug Administration (FDA) for its Phase 2 Clinical Trial.

The WSU/IBX collaboration has substantiated that:

1. A lower dose of the proprietary MagSense® HER2 Imaging Agent compared to the Phase 1 study is likely to be detectable, which is an important step for clinical development. Lower doses that still achieve the necessary detection sensitivity are expected to strengthen the product's safety profile, whilst also delivering a better care experience for patients.

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2. The WSU-optimised sequences improve upon the MRI sequences used in the Phase 1 study and will serve as the foundation for the imaging procedures deployed to sites participating in the planned Phase 2 study.
3. The use of quantitative imaging protocols in combination with molecular imaging agents may create AI-ready imaging data to improve and democratise diagnostic accuracy.

“We are delighted with the outcomes of the collaboration with Wayne State. Optimised protocols and a better understanding of minimum dosage give us further confidence as we move forward toward our planned IND application this year,” said Chief Business Officer Ward Detwiler. “Furthermore, the findings from quantitative MRI techniques that could unlock greater diagnostic precision through AI are extremely encouraging.”

MagSense® Manufacturing Progress Update

As previously disclosed, production of a new batch of the MagSense® HER2 Imaging Agent was completed. The Company is pleased to confirm that analytical testing of the Company’s proprietary MagSense® agent, in line with FDA guidance, is underway and is on track for the testing results to be completed and included in the IND. The new batch of the imaging agent will be available for use in the anticipated Phase 2 clinical study following regulatory approval of the IND application.

FDA Submission of IND for HER2 Breast Cancer Phase 2 Clinical Trial Remains on Schedule Q4 2024

Based on the current manufacturing MagSense® HER2 Imaging Agent and product release timeline, which remains in-line with previous market guidance, the Company expects the planned IND application to be submitted to the FDA in the current quarter of 2025. Commencement of the Phase 2 study is subject to approval of the IND by the FDA and is expected to start in Q1 2026.

Authorisation & Additional Information

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

— ENDS —

About Imagion Biosystems

Imagion Biosystems (ASX: IBX) is a clinical-stage, medical imaging company dedicated to transforming how cancer is diagnosed and treated. The company produced and is developing clinical applications for MagSense®, a first-of-its-class MRI imaging agent that enables clinicians to detect cancer earlier and with greater precision. Advancing molecular MRI, the company is using non-radioactive, bio-safe magnetic nanoparticles to improve diagnostic certainty for a broad range of applications, including HER2+ breast cancer, prostate cancers, and ovarian cancers. For more information, visit <https://imaginationbiosystems.com>.

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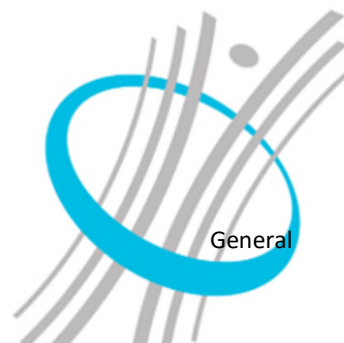
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