ASX ANNOUNCEMENT | 2 JUNE 2026

Imagion Biosystems Receives IND Clearance from US FDA

Key Highlights:

- Imagion receives written notice from the U.S. Food and Drug Administration clearing the IND for MagSense® HER2 Imaging Agent and allowing the Phase 1b/2 clinical trial in HER2+ breast cancer patients to proceed.
- The allowance marks a significant milestone for the company's advancement of the MagSense® platform.
- Phase 1b/2 trial patient recruitment anticpated to commence in Q3 2026, following site initiation activities.
- Clinical-trial site contracting underway as well as other key activities to support trial initiation.

Imagion Biosystems (ASX: IBX) (**Company** or **Imagion**), a company dedicated to improving healthcare outcomes through early and more accurate detection of cancers, is pleased to announce that the U.S. Food and Drug Administration (FDA) has issued a Study May Proceed Notice for the Company's Investigational New Drug (IND) application. The FDA has assigned IND number 165081 to the application. The FDA's allowance to proceed with the Phase 1b/2 clinical study in HER2+ breast cancer patinets indicates that the company has comprehensively addressed all necessary logistical, analytical, quality and safety pre-requisites necessary to conduct the trial.

The IND application included an extensive body of preclinical data, manufacturing and quality controls, as well as a detailed clinical trial protocol and procedures. The submission of an Investigational New Drug application represents a highly complex, resource intensive accomplishment that underscores Imagion's scientific rigour and execution capabilities. Successfully completing the review process and obtaining clearance of the IND underscores the safety and veracity of the trial and marks an important milestone for the Company.

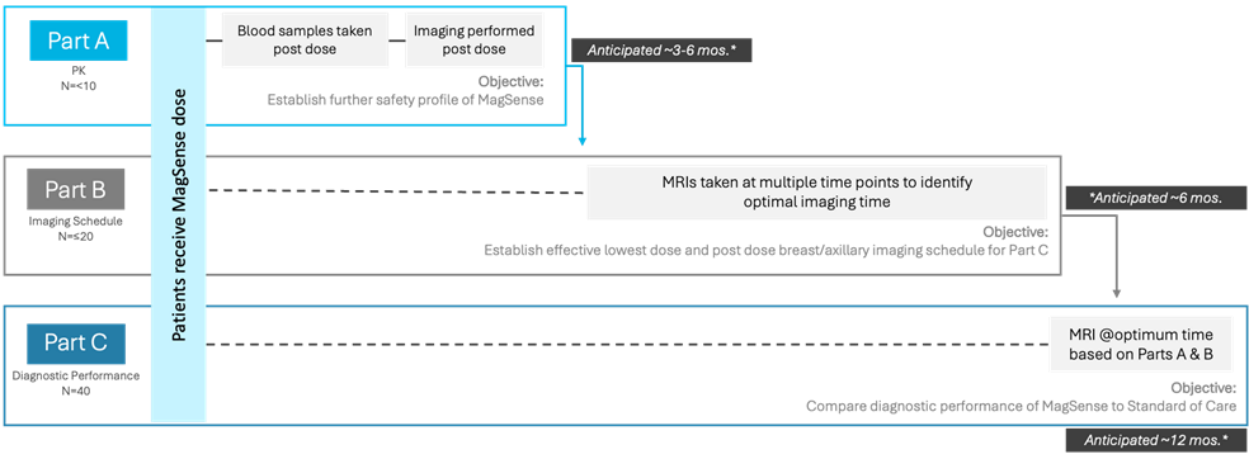
Commencing the Clinical Trial and Next Steps

The Company is moving forward with plans to initiate the Phase 1b/2 clinical trial for the MagSense® HER2 Imaging Agent in individuals with HER2+ breast cancer, and anticipates patient recruitment to commence during the third quarter of 2026, following site activation.

As previously announced, the Company has pre-selected and engaged necessary strategic trial partners required to manage the study. In parallel to the FDA's review of the IND, Imagion and its partners began the process of clinical-study site engagement, development of the support materials needed for clinical investigators, and progressing the logistic and data analysis methods to ensure full compliance with Good Manufacturing and Good Clinical Practices and other requisite regulations. Contracts with clinical sites can now be undertaken in concert with any institutional ethical or scientific reviews followed by commencement of participant enrolment.

Phase 1b/2 Clinical Trial Design

Designed in three parts, the trial will start with an initial cohort of subjects to collect additional safety data (Part A), as agreed with the FDA. The reduced dosing regimen and optimised imaging protocol will then be evaluated in a second group of subjects (Part B) before proceeding to a larger cohort of subjects to establish diagnostic performance (Part C). The trial for the MagSense® Imaging Agent in HER2+ Breast Cancer is expected to be completed in 18-24 months, with interim analyses anticipated after Part A and after Part B. In addition to evaluating the diagnostic performance of MagSense® for HER2+ breast cancer, the results of the trial will provide valuable insight into the potential impact on cost of care, patient outcomes, and overall clinical value. Additionally, by integrating quantitative imaging techniques into the protocol, the trial will yield critical data for the development and training of AI diagnostic tools.



Dr. Eghtedari at City of Hope hospital in Los Angeles, California will be the principal investigator (PI) for the trial. Dr. Eghtedari is Section Chief, Women's Imaging in the Department of Diagnostic Radiology at City of Hope. Dr. Eghtedari participated as an independent reviewer of the MagSense® HER2 Phase 1 study.

"This marks a significant milestone for Imagion and our stakeholders, validating both our science and strategic progress," said Ward Detwiler, President of Imagion's U.S. subsidiary. "MagSense has the potential to transform medical imaging by combining molecular-level precision with MRI's tissue visualisation capabilities. With FDA's Notice to Proceed, we can now commence our Phase 1b/2 trial, bringing MagSense® one step closer to potentially delivering meaningful impact for the many patients with HER2-positive breast cancer."

Why is the MagSense® HER2 Imaging Agent Phase 2 Trial important?

Each year, approximately 450,000 women receive a HER2 positive (HER2+) breast cancer diagnosis globally.[1] A HER2+ classification has significant prognostic and predictive implications for the patient because the HER2-positive subtype is considered an aggressive phenotype with a high rate of recurrence and metastasis. After a new cancer diagnosis,

[1] https://www.bcrf.org/breast-cancer-statistics-and-resources/

nodal staging is performed, which is a process that evaluates whether cancer has spread to nearby regional lymph nodes and involves a combination of clinical assessment and radiographic imaging. Precise nodal staging is an essential component in the management of patients with breast cancer, as treatments depend on patient specific characteristics of the primary tumour, nodal status, and evaluation for distant metastatic disease. There are variable practice patterns and imaging modalities employed based on available resources and institutional experience. The most commonly employed method is ultrasound, and whilst convenient and potentially lower cost compared to MRI, it faces a number of diagnostics challenges, resulting in wide variability in both sensitivity and specificity, as well as the limited ability to scan for the extent of the disease spread. Therefore, accurate nodal assessment to support early cancer diagnosis represents a critical unmet need.

In the successfully completed Phase 1 study, independent radiologists ascertained that the MagSense® HER2 Imaging Agent produced a readily identifiable change in MRI images to differentiate between tumour involved nodes and non-involved nodes. The Phase 1b/2 clinical trial will establish the optimised dose of the imaging agent, the optimum imaging timing, as well as assessing diagnostic performance.

The Phase 1b/2 trial represents a significant milestone for Imagion, providing multiple data outputs as MagSense progresses towards commercialisation.

About the MagSense® Imaging Agent Technology

MagSense® technology is a new class of MRI imaging agents that improves cancer detection compared to conventional imaging technologies by adding molecular specificity without using radioactivity. MagSense® agents will be the first imaging technology to use targeted magnetic nanoparticles to tag and detect cancers allowing for visualisation using MRI. This new class of imaging agents does not use ionising radiation or radioactive tracers and improves how medical imaging can be used compared to conventional imaging methods which only identify a region of interest using anatomical or morphological features but cannot differentiate benign tumours from malignant cancer. Imagion has developed MagSense® imaging agents for three different types of cancer. The lead product has completed a Phase 1 study for the detection of nodal metastases (spread) in HER2+ breast cancer and is now advancing into a Phase 1b/2 study. The MagSense technology is also extendable, with two additional agents for prostate cancer and ovarian cancer having been identified and could progress into IND-enabling studies as resources become available.

Authorisation & Additional Information

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

Join Imagion Biosystems' Investor Hub

Stay up to date on news and announcements or interact with our team through questions and comments via Investor Hub. Register at investor.imagionbiosystems.com.

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 imagionbiosystems.com.

Executive Chairman Contact Details
Bob Proulx
investor@imagionbio.com
AU: +61 3 9692 7222

Media Enquiries & Investor Relations
Erich Boileau, Boileau & Co.
imagionbio@boileau.co
US : +1 (616) 786-4461