ASX ANNOUNCEMENT | 26 August 2026

Phase 2 Clinical Trial Update: CRO work orders signed, MagSense® Agent ready for distribution

Key Highlights:

- Phase 2 clinical Trial work orders signed and startup activities underway with key CRO partners
- MagSense® investigational product manufacturing complete and ready for distribution to sites
- Contract negotiation with first USA clinical Trial site initiated
- Phase 2 Clinical Trial initiation activities underway with 7 prospective Trial sites
- Imaging protocol finalised with inclusion of advanced quantitative MRI techniques from WSU study

Imagion Biosystems (ASX: IBX) (**Company** or **Imagion**), a company dedicated to improving healthcare outcomes through earlier, more accurate, and non-invasive detection of cancers, is pleased to provide and update on its progress towards study initiation for the MagSense® HER2 Imaging Agent Phase 1b/2 Clinical Trial ("Trial").

The Company has now executed Work Orders with its primary study contract research organisation ("CRO"), as well and with CROs managing imaging and pathology responsibilities for the Trial. These key relationships are important to ensure the integrity and clinical compliance of the study and allow the company to accelerate its progress towards study startup, advancing key activities for site selection and onboarding, data management, site and investigator training, and participant recruitment strategies. The Company has begun study initiation activities with seven prospective Trial sites, with contract negotiation underway with its first site after receiving confirmed intent to participate from the site's clinical team.

Manufacturing of the MagSense® HER2 investigational product ("IP") has been completed, with the IP passing its requisite stability testing, and distribution logistics for the study in place. This allows for timely delivery of the material to all engaged sites ahead of patient enrollment. Additionally, the study imaging protocol has been finalised, with the inclusion of advanced quantitative imaging techniques developed through the previous research engagement with Wayne State University and validated for clinical adoption through the company's collaboration with Siemen's Healthineers.

"Since receiving our IND clearance and Study May Proceed notice from the U.S. FDA in June, the Imagion team and its key Trial partners have been laser focused on Trial initiation activities," said Imagion Biosystems, Inc. President Ward Detwiler. "We have been making tremendous progress towards study start-up and look forward to opening the Clinical Trial for enrolment as quickly as possible."

While working towards finalisation of Trial site contracting, the company and its study partners will proceed with remaining study startup activities, including relavant Institutional Review Board (IRB) approval(s), registration with ClinicalTrials.gov, investigator training, and IP shipment, before formally opening the study for enrolment.

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, 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.

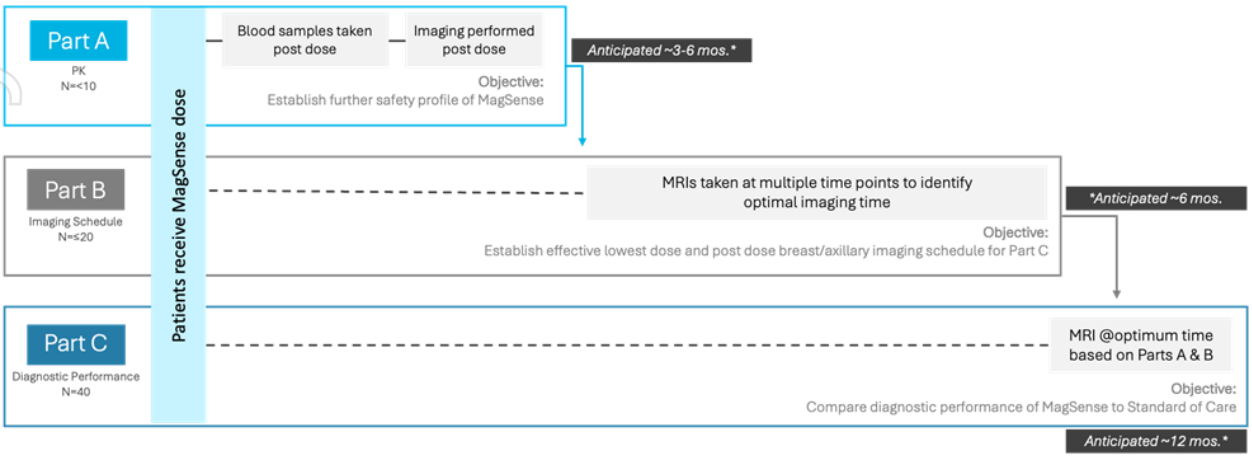
In the successfully completed Phase 1 study, independent radiologists ascertained that the MagSense® HER2 Imaging Agent produced a readily identifiable change in MRI images to differentiate between tumour involved nodes and non-involved nodes. The Phase 1b/2 clinical Trial will establish the optimised 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.

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.

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



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.

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 ionizing 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.

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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.

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