ASX ANNOUNCEMENT | 17 NOVEMBER 2026

Imagion Executes First US Site Agreement for Phase 1b/2 Clinical Trial of MagSense® Imaging Agent for HER2+ Breast Cancer

Key Highlights:

- Imagion has executed a Clinical Trial Agreement with Regis Clinical Research, the first site formally engaged for the MagSense® HER2+ Imaging Agent Phase 1b/2 clinical trial.
- The Clinical Trial Agreement with Regis marks a critical milestone towards the trial initiation and advancement of the MagSense® platform.
- Regis is an independent clinical research site focused on efficient clinical trial execution and a core focus on oncology.
- Phase 1b/2 clinical trial patient recruitment is anticipated to commence shortly, following site initiation activities.
- Clinical trial site initiation activities underway at seven total sites.
- The MagSense® HER2 Imaging Agent Phase 1b/2 clinical trial is now active on ClinicalTrials.gov.

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 it has secured its first clinical trial site for the MagSense® HER2 Imaging Agent Phase 1b/2 trial, following execution of a Clinical Trial Agreement with oncology-focused Regis Clinical Research.

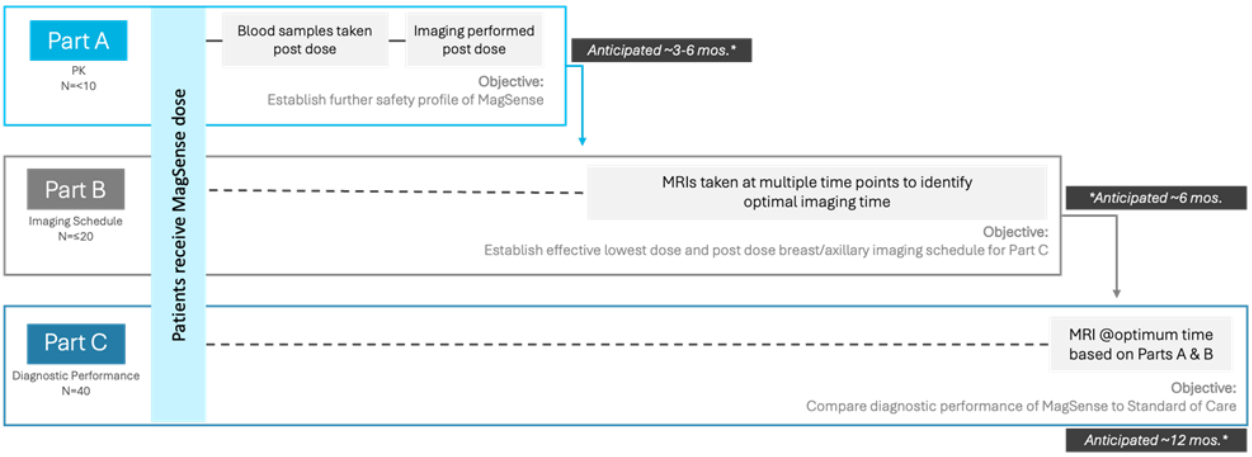
The agreement enables Imagion and Regis to progress immediately towards site activation and patient recruitment, representing a key milestone towards clinical trial initiation. The clinical trial has also been formally registered on ClinicalTrials.gov, marking another important step in the clinical development of the MagSense® HER2 Imaging Agent and broader MagSense® platform.

“Bringing our first clinical trial site under contract marks an important step in progressing our clinical program,” said Imagion’s US subsidiary President Ward Detwiler. “Regis’ extensive oncology clinical trial experience and focus on efficient execution make it a strong fit as we move towards initiation.”

With the first site contracting completed, the Company is proceeding towards site-specific clinical trial startup activities, including investigator training and site activation. Beyond Regis, a total of seven sites have been selected to participate in the clinical trial to date, with the Company focused on moving these additional sites towards contract finalisation and activation as efficiently as possible.

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 clinical trial.

Why is the MagSense® HER2 Imaging Agent Phase 1b/2 clinical 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+ 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

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

experience. The most commonly employed method is ultrasound, and whilst convenient and potentially lower cost compared to MRI, it faces numerous diagnostic 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 clinical trial, 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 clinical 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 clinical trial for the detection of nodal metastases (spread) in HER2+ breast cancer and is now advancing into a Phase 1b/2 clinical trial. 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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