

ASX ANNOUNCEMENT | 30 September 2026

Imagion Biosystems Secures Central Ethics Approval, Clearing Key Phase 2 Trial Startup Milestone

Key Highlights:

- Central Institutional Review Board (IRB) ethics approval received for Imagion's Phase 2 MagSense® trial in HER2-positive breast cancer, clearing a key ethics and regulatory hurdle
- Protocol, informed consent forms and all study materials approved by Advarra IRB, enabling advancement to active site initiation and patient recruitment
- Use of a single central IRB process streamlines activation across multiple participating clinical sites, supporting efficient site activation and enrolment
- Site activation activities are underway, with patient enrolment to commence following first site activation
- Achievement of this milestone materially advances the Company's clinical development program and supports progression towards generating Phase 2 efficacy and safety data

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 Advarra, Inc. has granted central Institutional Review Board (IRB) ethics approval for the Company's Phase 1b/2 clinical trial of the MagSense® HER2 Imaging Agent.

Central IRB approval represents a significant milestone and clears a key ethics and regulatory requirement prior to patient enrolment. Together with the previously announced United States Food and Drug Administration (FDA) Investigational New Drug (IND) clearance, it solidifies the approvals necessary to commence the trial in the United States. Advarra's review confirms that the study protocol, informed consent process and participant safeguards meet U.S. ethical and regulatory standards for clinical research involving human participants.

The use of a central IRB is intended to streamline trial start-up and support efficient trial execution. Participating sites may rely on the central IRB ethics approval, where permitted, rather than conducting separate full ethics reviews, reducing duplication and facilitating more rapid site activation and patient enrolment.

"Central IRB approval is an important milestone as we progress towards study activation and it reflects the disciplined work of our team in designing and preparing for this clinical trial," said Ward Detwiler, President of Imagion's U.S. operations. "With both regulatory and ethics approvals now secured, our focus remains on completing the final stages of site activation and advancing towards opening the study for patient enrolment."

The Company and its clinical trial partners are now finalising site activation activities, including site contract execution, investigator training, and patient recruitment planning, with first patient enrolment to commence following first site activation.

About the MagSense® Imaging Agent Technology

MagSense® technology is a new class of MRI imaging agents that aims to improve 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 potentially tag and detect cancers allowing for visualisation using MRI. This new class of imaging agents does not use ionising radiation or radioactive tracers and aims to improve how medical imaging can be used compared to conventional imaging methods which cannot differentiate benign tumours from malignant cancer. Imagion has developed MagSense® imaging agents for potential use in three different types of cancer. The lead product has successfully completed a Phase 1 study for the detection of nodal metastases (spread) in HER2+ breast cancer and is now advancing into the planned Phase 1b/2 study. The MagSense® technology platform has the potential to expand into two additional indications, being prostate cancer and ovarian cancer.

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 aims to enable clinicians to detect cancer earlier and with greater precision. Advancing molecular MRI, the company is using non-radioactive, bio-safe magnetic nanoparticles to potentially 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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