

IMAGION BIOSYSTEMS LIMITED

(ASX: IBX)

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Imagion to proceed to file an IND for the MagSense HER2 Imaging Agent following FDA feedback

MELBOURNE — **Imagion Biosystems Limited (ASX: IBX)**, a company dedicated to improving healthcare through the earlier detection of cancer, is pleased to provide an update on development plans for its MagSense® HER2 imaging agent. Based on feedback the Company has received from the U.S. Food and Drug Administration (FDA), the Company plans to proceed with a multi-site Phase 2 clinical trial in the US. The Phase 2 study will investigate various clinical endpoints while optimizing dose and imaging parameters, which will be necessary before committing to a Phase 3 pivotal study.

The Company has previously reported favourable interim safety and tolerability data from its Phase 1 clinical study and had undertaken an independent expert review to corroborate the prospective ability of its MagSense HER2 Imaging Agent to detect suspicious nodes using Magnetic Resonance Imaging (MRI) in patients with HER2-positive breast cancer ([link to announcement](#)). The Phase 1 data and independent review have provided the foundation for the Company now to pursue use of the MagSense® nanoparticle technology for molecular imaging of cancer with mainstream MRI detection.

Expanding clinical trials into the U.S. requires filing an Investigational New Drug (IND) application with the FDA. As previously disclosed, the Company had initiated communication with the FDA earlier this year and is now pleased to report that the feedback from the FDA is in agreement with the key elements of the Company's proposed Phase 2 study design and provided further guidance and recommendations as it relates to the completeness of the Company's nonclinical and clinical Phase 1 data package which would form part of the IND application. The Company notes that the guidance and recommendations are consistent with regulatory oversight for products entering Phase 2 of clinical investigations.

The FDA guidance is an important milestone that enables the Company to proceed with preparing and filing the IND. Accordingly, activities in the coming quarters include:

- Collecting additional non-clinical and clinical data (pharmacokinetics) in support of commencing a US Phase 2 study;
- Manufacturing additional MagSense® HER2 imaging agent material to support the US Phase 2 study; and
- Establishing the initial clinical investigators and sites to support the study.

The Company expects to be able to file the IND submission in Q4 of 2023 or Q1 of 2024.

"Receiving this early feedback from the FDA was very important as we prepare for the IND filing later this year, yet another major milestone for our imaging technology and pipeline development," said Bob Proulx, Imagion's CEO. Adding "The FDA feedback provides clarity for our actions in the coming months, including our plans to use our new facility for part of the manufacturing process. This is something we anticipated when we embarked on upgrading our manufacturing and R&D operations early last year and are now pleased to see coming to fruition. It is also very gratifying to see the Phase 1 study data being used to support our next phase of development."

The Company also notes that MagSense® HER2 Breast Cancer Phase 1 study remains open with additional enrolment occurring since the last announcement. The Company looks forward to keeping investors updated with its progress towards the next phase of clinical investigations.

Imagion Biosystems Limited

ACN 616 305 027

Level 25, 525 Collins Street, Melbourne VIC 3000
www.imagionbiosystems.com



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About Imagion Biosystems

Imagion Biosystems is developing a new non-radioactive and safe diagnostic imaging technology. Combining biotechnology and nanotechnology, the Company aims to detect cancer and other diseases earlier and with higher specificity than is currently possible. Imagion Biosystems listed on the Australian Securities Exchange (ASX) in June 2017.

For further information visit <https://imaginationbiosystems.com/our-technology/technology-shift-fags/>

Authorisation & Additional information

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

U.S. Media Contact:

Casie Ost

Casie.ost@imaginationbio.com

+1-619-693-4428

Australian Media & Investor Relations:

Hannah Howlett, WE Communications

We-AUImaginationBiosystems@we-worldwide.com

+61 (0) 450648064