Company Announcement

IMAGION BIOSYSTEMS LIMITED

ASX: IBX

21 June 2023

Imagion set to complete the MagSense® HER2 Phase 1 Study

Highlights

- **Study achieves enrolment target**
- **Study to formally close to new enrolments on 31 July**
- **Study results support further clinical development as MRI imaging agent**

MELBOURNE — **Imagion Biosystems Limited (ASX: IBX),** a company dedicated to improving healthcare through the earlier detection of cancer, is pleased to report that the MagSense® HER2 imaging agent Phase 1 study (IBI10103) has achieved its enrolment target and that the Company has initiated its plans to close the study as was indicated in the Company's AGM held on 25th May 2023.

"Completing the target enrolment numbers for the Phase 1 study is a great achievement for our first clinical study," said Bob Proulx, Imagion's CEO. "Whilst recruitment has been challenging, by all accounts the Phase 1 study has been a success, and we truly thank the breast cancer patients that volunteered to participate and the study investigators and staff that have diligently worked with us. We have truly broken new ground, having done something in medical imaging never done before. This now provides strong footing for us to move ahead with our HER2 breast cancer program and with the confidence that we have a unique platform in our targeted nanoparticle technology to develop imaging agents for other types of cancer."

The study has been instrumental in revealing the potential clinical utility of the MagSense® HER2 Imaging Agent and confirmation that the Company's targeted nanoparticle technology has the potential to change how MRI can be used to specifically detect cancer. A total of thirteen patients have been enrolled to-date, meeting the original goal of 10 -15 patients, and the Company now intends to close enrolment effective July 31st. Any additional patients enrolled between now and the end of July will complete their follow ups as per the protocol schedule of events.

The Company, with its investigators, plans to publish results from the study in due course and will use the data in support of an Investigational New Drug (IND) application expected late this year or the beginning of 2024. To-date, the emerging data are supportive of the Phase 1 study objectives, and include:

- Safety and tolerability - there having been no safety issues, toxicity or adverse events reported related to the imaging agent;

Imagion Biosystems Limited
ASX:IBX ACN 616 305 027
Level 25, 525 Collins Street, Melbourne VIC 3000
www.imagionbiosystems.com | investor@imagionbio.com

- Detectability - the MagSense® imaging agent is detectable by both imaging methods employed in study, the Company's proprietary magnetic relaxometry technology and conventional Magnetic Resonance Imaging (MRI); and
- Potential Utility – the change in image contrast in nodes highly suspicious for tumour is distinctly different from the contrast seen in non-involved nodes.

The assertion that the MagSense® imaging agent provides new information for the radiologist not available through ultrasound, which is currently used as standard of care, has been corroborated by an independent panel of expert radiologist.

IND and Phase 2 study

In March 2023 the Company received feedback from the FDA pertaining to its clinical development plans and intent to proceed with a multi-site Phase 2 study in the U.S. The Phase 2 study will be used to optimize dose and imaging schedules as well as explore various endpoints for clinical validity.

As part of the preparation for the IND filing and subsequent Phase 2 clinical trial the activity and upcoming milestones are outlined below.

- Manufacturing new lot of the MagSense® HER2 imaging agent;
- Complete IND enabling studies in line with FDA guidance; and
- Establish lead U.S investigator(s) and initial site(s)

Additionally, the Company seeks to recruit one or two additional patients in a satellite cohort under an already approved amendment to the Phase 1 Study to explore the imaging of nodes after they have been removed from breast cancer patients under current standard surgical practices. The exploration of such ex vivo imaging has been encouraged by the FDA. These data, from even a small number of patients, could be included in the data package being prepared for the FDA and could be used to establish methods to evaluate node level correlation between MRI findings and pathology in the Phase 2 study.

— ENDS —

About Imagion Biosystems

Imagion Biosystems is developing a new non-radioactive and precision diagnostic molecular imaging technology. Combining biotechnology and nanotechnology, the Company aims to detect cancer and other diseases earlier and with higher specificity than is currently possible.

For more information, visit https://imagionbiosystems.com/investor-hub/

Imagion Biosystems Interactive Investor Hub

Engage with us directly by asking questions, watching video summaries, and seeing what other shareholders have to say about this and past announcements at our Investor Hub:
https://investorhub.imagionbiosystems.com/

Imagion Biosystems Ltd.
ASX:IBX ACN 616 305 027
www.imagionbiosystems.com

Authorisation & Additional information

This announcement was authorised by the Disclosure Committee of Imagion Biosystems Limited

Australian Media & Investor Relations:
Hannah Howlett, WE Communications
We-AUImagionBiosystems@we-worldwide.com
+61 450 648 064

U.S. Media Contact
Casie Ost
casie.ost@imagionbio.com
+1-619-693-4428