

IMAGION BIOSYSTEMS LIMITED

(ASX: IBX)

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MagSense® HER2 Breast Cancer First-in-human Study Progress Update

- Interim data supports MagSense® imaging agent is safe and well tolerated
- Results make evident that the imaging agent is reaching the patient's lymph nodes

MELBOURNE — Imagion Biosystems Limited (ASX: IBX), a company dedicated to improving healthcare through the earlier detection of cancer, is pleased to provide this update on the progress of its first-in-human study for the MagSense® HER2 breast cancer imaging agent.

The study is intended to investigate the potential for the MagSense® HER2 targeted imaging agent to be used for nodal staging of HER2 positive breast cancer by detecting if tumour cells have metastasized to the lymph nodes. Currently, nodal staging requires a patient's lymph nodes to be surgically biopsied for histopathological examination.

To date, our investigators have completed an evaluation of the first five patients that have completed the study. Dr. Jane Fox, the study Principal Investigator from Monash Health stated, "We can say that there have been no safety issues reported related to the MagSense® HER2 imaging agent and that all patients have tolerated the administration and dosage of the injectable". Dr Fox added, "we have observed that the imaging agent, as administered, is capable of reaching the lymph nodes."

Bob Proulx, Executive Chairman of Imagion Biosystems said, "we are encouraged by these preliminary observations from our investigators. It is very exciting to begin accumulating patient data and see the positive direction of these preliminary results. We feel the results from the first five patients provide sufficient justification for us to continue the study. We sincerely want to thank the patients that have selflessly volunteered to participate to date."

Based on the observations to date, the Company plans to move forward with scale-up activities to support further development and clinical studies that would support regulatory submissions. If one of the imaging methods is shown to be effective in pivotal studies, the MagSense® HER2 test would be commercialized as a non-invasive alternative reducing the need for biopsies for nodal staging.

About the Study

As it is the first clinical investigation of the Company's MagSense® technology the study was designed to be a small proof-of-principle study with the primary objective of achieving an initial assessment of the safety and tolerability of the MagSense® injectable imaging agent. A secondary objective of the study is the confirmation that the route of administration is effective in allowing the imaging agent to reach the patient's lymph nodes.

Each patient in the study receives an injection of the MagSense® HER2 targeted imaging agent and evaluation by two imaging modalities: magnetic resonance imaging (MRI) and our proprietary magnetic relaxometry (MRX) technology. The exploratory objectives of the study include a comparison of the MRI and MRX results to standard clinical tissue histopathology to achieve a preliminary assessment as to whether the MagSense® HER2 imaging agent when used with one or both imaging modalities might be able to provide a non-invasive alternative to nodal biopsy. The study intends to enrol approximately 15 patents, allowing the Company to assess preliminary clinical investigative questions before committing to larger enabling studies.



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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 please visit www.imagionbiosystems.com

Authorisation & Additional information

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

U.S. Media Contact:

Casie Ost
Casie.ost@imagionbio.com
+1-619-693-4428

Australian Media & Investor Relations:

Hannah Howlett, WE Communications
We-AUImagionBiosystems@we-worldwide.com
+61 (0) 450648064