



IMAGION BIOSYSTEMS LIMITED

(ASX: IBX)

26 May 2021

First-in-human study update: First patient enrolled

MELBOURNE — Imagion Biosystems Limited (ASX: IBX), a company dedicated to improving healthcare through the earlier detection of cancer, is pleased to announce that the first patient has been enrolled in the MagSense® HER2 breast cancer Phase I first-in-human study.

The study, which is expected to enroll approximately 15 patients, is the first clinical investigation of Imagion Biosystems' MagSense® nanoparticle technology. This study investigates the use of a MagSense® imaging agent as a means of aiding in the staging of HER2 positive breast cancer by detecting if the patient's tumor has spread to the lymph nodes. Current standard of care requires biopsy or surgical removal of lymph nodes to confirm metastases. With approximately half of HER2 breast cancer patients having no nodal disease, the MagSense® HER2 test achieved Breakthrough Device designation from the US FDA based on its potential to provide a non-invasive way to eliminate unnecessary surgical biopsy procedures and their resultant morbidities.

"We are very pleased to report our first patient has been enrolled in this ground-breaking study," said Bob Proulx, Executive Chairman of Imagion Biosystems. "Though recruiting newly diagnosed cancer patients into a research study can be challenging, we and our investigators remain confident we will reach our recruitment target. We are committed to explore all avenues to achieve our goal of completing this important study."

Each patient in the study receives an injection of the MagSense® nanoparticle imaging agent and undergoes imaging by MRI. Additionally, a sample of the lymph node is also assessed using Imagion's proprietary MagSense® magnetic relaxometry technology. The primary endpoint of the study is to determine the safety and tolerability of the MagSense® imaging agent, but the study will also explore the effectiveness of the nanoparticles for *in vivo* detection which will inform further development and commercial considerations.

Full study details can be found at [ANZCTR](#) under study ID: IBI010103.

-ENDS

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:

Matthew Wygant
matthew@biotechwriting.com
+1-408-905-7630

Australian Media & Investor Relations:

Kyahn Williamson, WE Communications
We-AUImagionBiosystems@we-worldwide.com
+61 (0) 401018828

Imagion Biosystems Limited

ACN 616 305 027
Level 25, 525 Collins Street, Melbourne VIC 3000
www.imagionbiosystems.com