



Imagion Biosystems Reports Progress on Regulatory Pathway

MELBOURNE — April 4, 2018 — Imagion Biosystems Limited (ASX:IBX), a company dedicated to improving healthcare through the earlier detection of cancer, is pleased to provide an update on recent communications with the U.S Food and Drug Administration (FDA) regarding its plans for clinical development of MagSense™ technology.

Following FDA guidance for medical devices, Imagion filed a Pre-Submission document with the FDA in January 2018 to initiate communications regarding the Company's clinical development plans. Pre-Submissions are optional filings with the FDA but are encouraged, particularly for new technology medical products, to foster open communication and dialog with the agency. The FDA provides written feedback on Pre-Submissions within 3 months, which the Company recently received, confirming key aspects of the Company's development plan:

- The Center for Devices and Radiological Health (CDRH) confirmed the Office of Combination Products' opinion that the MagSense system is a combination product and that CDRH is the lead review group;
- The CDRH accepted Imagion's general toxicology study plan based on the view that the nanoparticle formulation represents a low safety risk due to prior known safety profiles of the materials incorporated into the formulation;
- The CDRH agreed with Imagion's overall clinical study approach of sequential clinical studies starting with the first-in-human Early Feasibility Study and provided clear guidance for the Early Feasibility Study Design.

"We are very happy with the feedback we received and the level of engaged dialog with the FDA in our Pre-Submission process," said Bob Proulx, Executive Chairman of Imagion Biosystems. "This communication gives us confidence that our clinical development plan is on solid ground and in sync with the expected regulatory requirements."

Key next steps in the development process required before first-in-human testing include:

- Manufacturing an initial batch of GLP-compliant MagSense nanoparticles;
- Undertaking a nanoparticle safety and toxicology study.

About Imagion Biosystems

Imagion Biosystems is at the crossroads of biotechnology and nanotechnology. Its novel bioimaging and nanomagnetic detection systems have been developed specifically to detect cancer and other diseases earlier and with higher specificity than is currently possible. With MagSense™ technology, the company has the potential to optimize patient care and reduce mortality rates across various cancer indications. Imagion Biosystems listed on the Australian Securities Exchange (ASX) in June 2017.

For further information please visit www.imagionbiosystems.com



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