

ASX Announcement 10 October 2017

Imagion Biosystems Secures Nanoparticle Manufacturer

Contract manufacturer ChemConnection to produce first formulations for clinical use

MELBOURNE — 10 October 2017 — Imagion Biosystems Limited (Imagion, ASX:IBX) has entered into a Master Service Agreement with ChemConnection BV, a Dutch contract manufacturing organisation (CMO), to produce and supply clinical grade MagSense™ nanoparticle formulations for the Company's planned HER₂ breast cancer human clinical studies.

ChemConnection is a highly qualified development and manufacturing organisation based in Oss, the Netherlands, with extensive experience in producing nanoparticle-based products and medicines. The CMO will establish manufacturing procedures for the MagSense™ HER₂ breast cancer test formulation that will meet the globally recognised standard of Current Good Manufacturing Practices (cGMP), a regulatory requirement for human testing.

Method transfer of the proprietary nanoparticle formulation will commence immediately. The CMO's first deliverable will be the production of a pilot lot of material which will be used for the stability and toxicity studies that are needed before first-in-human testing can begin. The safety toxicology studies are expected to be able to commence in the first quarter of 2018.

"Finding the right partner to outsource the manufacturing of our nanoparticles was critical to our development plan," said Robert Proulx, CEO of Imagion. "ChemConnection has both the experience working with our type of materials and formulations, and the quality systems in place to meet regulatory requirements. We now have qualified medical device manufacturing partners in line for both the instrument and nanoparticles, which will enable us to meet our goal of first-in-human testing for the MagSense™ technology before the end of next year."

Imagion's core MagSense™ technology will use the tiny bio-safe nanoparticles to be produced by ChemConnection to 'tag' cancers, which can then be detected by the Company's highly sensitive magnetic sensors to locate and characterise tumours at their earliest stages.

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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 optimise patient care and reduce mortality rates across various cancer indications. Based in Albuquerque, New Mexico, Imagion Biosystems listed on the Australian Securities Exchange (ASX) in June 2017.

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