### **ASX Announcement**

# Application to Singaporean Health Services Authority to begin commercial implants of Angel Medical System's Heart Attack Alert Device

Hydrix Limited (ASX: HYD) ('Hydrix'), today advised that leading Singaporean cardiologist Dr. Leslie Lam has lodged a *GN-26 application (import and supply of unregistered medical devices by request of qualified practitioners)* (**GN-26 application**) with the Singapore Health Sciences Authority (HSA) for approval to begin commercial implants of the Guardian® System heart attack alert device in Singapore in the first quarter of 2020.

On 2 October 2019, Hydrix announced that it had acquired the exclusive rights to distribute the Guardian System manufactured by Angel Medical Systems, Inc. in eight Asia Pacific countries. The Guardian System is the world's first FDA-approved implantable heart attack alerting device. Subject to approval of this GN-26 application by the HSA, Hydrix anticipates Dr. Lam could begin commercial implants as soon as the first quarter of 2020.

The GN-26 scheme enables healthcare providers to import devices to treat specific patients, prior to them achieving full regulatory approval in Singapore. Dr. Lam, who practices cardiology at the prestigious Farrer Park Medical Centre in Singapore, will be Hydrix's first customer to undertake commercial implants of the Guardian device in South East Asia. Dr. Lam is a Governor of the US Society for Cardiac Angiography & Interventions.

In speaking about the Guardian device, Dr. Lam said "The Guardian is the world's first FDA approved implantable heart attack alert device. Its unique ability as an early warning system of an impending heart attack meets an unmet need in the market. It offers potential to significantly improve cardiac care and quality of life for my patients. In addition to alerting a patient of an impending heart attack, the Guardian detects other cardiac events, including arrhythmias. I'm very pleased to become the first customer of Hydrix to implant the Guardian device in Singapore."

In support of the anticipated Singapore market launch in the first quarter of 2020, Hydrix will host a key opinion leader symposium at the 29<sup>th</sup> Singapore *LIVE* in January 2020, the pre-eminent cardiac interventions conference for South East Asia. The panel will be chaired by Dr. Lam, with key note addresses from the Founder & CEO of Angel Medical Systems Dr. David Fischell; interventional cardiologist, President of the Baim Institute and former Professor of Harvard Medical School Dr. Michael Gibson; and Chief of Cardiology Spectrum Health Medical Group and President of American College of Cardiology Dr. David Wohns. The panel will present on, and discuss, the potential 'time-to-door' patient and health economic benefits of the Guardian device.

Gavin Coote, Chairman of Hydrix said that "We are delighted to have engaged such a highly regarded cardiologist as Dr. Leslie Lam as our first customer to undertake commercial implants of the Guardian device. Dr. Lam's GN26 submission and impending HSA approval to begin commercial implants in Singapore represents a strong commercial endorsement and will help raise awareness among other cardiologists of the potential benefits for their patients. Hydrix and Angel Medical System's attendance at the upcoming symposium is expected to generate significant additional interest throughout Southeast Asia."

#### -ENDS-

For more information, contact: info@hydrix.com



## **ASX Announcement**

**18 November 2019** 

## **About Hydrix Limited**

Hydrix (**ASX: HYD**) is a product design and engineering company, specialising in complex, regulated and safety-critical projects. We partner with clients to help design, develop and commercialize transformative medical device, consumer, industrial, defence and aerospace products. For more information, please visit: www.hydrix.com

#### **About The Guardian System**

The Guardian System® by AngelMed is an implantable cardiac monitor with patient alerting capability and an additional external alarm device. The Guardian System is indicated for use in patients who have had prior acute coronary syndrome (ACS) events including heart attacks, and who remain at high risk for recurrent events. Implanted like a single chamber pacemaker, the Guardian System detects potential ongoing ACS events, characterized by sustained ST segment changes that may indicate a coronary occlusion. The Guardian then alerts the patient to seek medical attention with a vibrational alert from the implant as well as sounds and a flashing LED from a separate pager-like device.

A Guardian System alert is a more accurate predictor of ACS events when compared to patient recognized symptoms alone and demonstrates a reduced rate over time of patient presentations without ACS events (false positives) when compared to patient recognized symptoms alone.

Solving an unmet medical need for better diagnosis of a life-threatening condition, the Guardian provides the first ever means of prompting patients to seek medical attention for silent heart attacks and ACS events having no symptoms at all.