

## **AngelMed receives USA FDA approval for the Guardian® device.** **Hydrix to submit local regulatory approval applications.**

### **Key Highlights:**

- The US Food and Drug Administration has approved the upgraded battery for the AngelMed Guardian for commercial release in the USA
- The Guardian is the world's only implantable cardiac monitor intended to detect and alert patients of a potential heart attacks (including a silent heart attack)
- Approval paves the way for Hydrix to submit applications for regulatory and healthcare reimbursements, commencing with Australia and Singapore.
- Hydrix's market opportunity for the approved Guardian implant is substantial

Hydrix Limited (ASX: HYD, '**Hydrix**' or the '**Company**') has been advised by Angel Medical Systems Inc. ('**AngelMed**') that the Guardian System AMSG3-E ('**Guardian**') has been approved by the U.S. Food and Drug Administration (FDA) for commercial release in the USA.

Hydrix Executive Chairman Gavin Coote said "This is a brilliant outcome for AngelMed and Hydrix. The Guardian is a game-changer in cardiac monitoring. It is the world's only implantable device that can alert a person of an impending heart attack and has the potential to transform patient quality of life. The FDA approval clears the way for Hydrix to complete regulatory submissions in Asia-Pacific markets commencing with Australia and Singapore."

Hydrix is the exclusive distributor of the AngelMed Guardian in eight Asia Pacific countries including Australia, Singapore, Japan, Malaysia, Hong Kong, Thailand, Indonesia, and New Zealand.

AngelMed CEO, Brad Snow, commented after the announcement "this is a great achievement for the AngelMed team who have worked tirelessly to make this day a reality. We are excited to commercially launch within weeks in the USA and look forward to supporting Hydrix with its plans to expand our reach into the Asia Pacific market and partner with us to develop next generation device features."

The AngelMed Guardian continuously monitors a patient's heart signal 24/7 uniquely against the patient's own baseline heart signal. It is the world's only FDA-approved, implantable cardiac monitoring device and alerts patients of an impending Acute Coronary Syndrome (ACS) event, including against deadly silent heart attacks.

The Guardian identifies ACS symptoms with more certainty than patient recognition of symptoms alone and alerts them to immediately seek medical help. It has also been proven to significantly help reduce unnecessary attendance at an emergency department arising from false patient symptoms; a helpful benefit in an uncertain COVID environment. Patients implanted with the device have been shown to have an improved quality of life, as they feel safer, more in control, and less anxious.

The Guardian has shown a reduction in Time-to-Door to receive treatment (confirmed ACS symptoms to hospital attendance) a critical metric in improving long term patient outcomes. The quicker a heart attack is recognised and treated, the greater the chance of recovery by the patient.

### **Hydrix Medical Regulatory & Reimbursement Process**

The FDA approval is the key milestone for Hydrix Medical to submit applications for regulatory approvals in Australia and Singapore. The Australian TGA regulatory approval process is anticipated to take 6-12 months and the Singapore HSA regulatory approval process 9-12 months. These are indicative timeframes only.

Hydrix Medical has commenced the Medical Services Advisory Committee (MSAC) application process in Australia to establish a surgical code for the reimbursement of fees pertaining to implant procedures. The Company will also begin the Prostheses List Advisory Committee (PLAC) process to establish a device reimbursement code for the Guardian following submission of the TGA application.

### **Market Opportunity for Hydrix Medical**

Cardiovascular disease afflicts 14% of the global population, and at 31%, is the leading cause of death. On average, the probability of death from an initial heart attack is one in ten, this probability doubles to one in five for subsequent attacks. Approximately 45% of heart attacks appear to be clinically silent, those events not associated with any symptoms that a patient can recall.

Within Hydrix Medical's exclusive distribution territories, there are more than 500,000 acute coronary syndrome events annually, the patient cohort most likely to benefit from an early warning heart attack alert system. For context, a 1% market share in countries that Hydrix is targeting has the potential to generate \$35 million in annual sales revenue for Hydrix Medical.

### **Update on Australian AngelMed Guardian implants and Phyzhon's First In-Human (FIH) trial**

FDA approval further enables documentation and mapping of regulatory approval processes in New Zealand, Malaysia, Hong Kong, Thailand, Indonesia, and Japan. Ongoing discussions with prospective sub-distributors in these jurisdictions are progressing.

Hydrix continues to work towards commencing local implants of the AngelMed Guardian and the First In Human trials of Phyzhon Health's PHYRARI FFR Guidewire.

AngelMed implants are classified as elective surgery procedures. Due to intermittent and ongoing COVID lockdowns and associated disruptions, efforts to commence special access scheme implants are being impacted.

The fluidity of the situation is not dissimilar to that leading into the Singapore implants of the Guardian last year. Hydrix remains confident that these milestones will be realised, and we look towards the September quarter.

Hydrix also continues to evaluate numerous growth opportunities to expand the cardiovascular and medical device product portfolio within Hydrix Medical.

This announcement is authorised for release by the Board of Directors of Hydrix Limited.

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**About Hydrix Limited**

Hydrix Limited (ASX: HYD) is a powerful product innovation company. Hydrix purpose is to enhance the health, safety, and wellbeing of one Billion lives. The company leverages its powerful product innovation capability across multiple growth platforms: **Hydrix Services** design and engineer client products which transform industries; **Hydrix Ventures** generate equity returns through investing in high potential companies; and **Hydrix Medical** bring innovative medical technologies to market.