ASX Announcement **27/02/2023**

Hydrix withdraws its Guardian regulatory application with a view to resubmitting to the Australian TGA at a later date

Hydrix Limited (ASX: **HYD**) (**Hydrix** or the **Company**): advises today, that after application review by, and engagement with, the Australian Therapeutic Goods administration (TGA), in the Company's view, the best path forward to reach an approval with the TGA, is to withdraw the current application with a view to resubmitting at a later date.

Whilst the TGA acknowledged Guardian device benefits, our understanding in principle is, they are not yet convinced that the patient benefits sufficiently outweigh potential risks from using an endocardial lead (used in pacemaker implants), in the Australian context. The Guardian uses the pacemaker lead to continuously monitor the heart to detect and alarm a patient of a life-threatening cardiac event. Angel Medical Systems will continue to gather patient data to assist Hydrix with a view to resubmitting to the TGA in due course.

This decision does not impact the current revenue and earnings of Hydrix or commercial sales of the Guardian in Singapore and Malaysia where we already have regulatory approvals. The decision does not reduce our activity in seeking regulatory approvals in the large markets of Indonesia, Japan, and Thailand and the strategic market of Hong Kong.

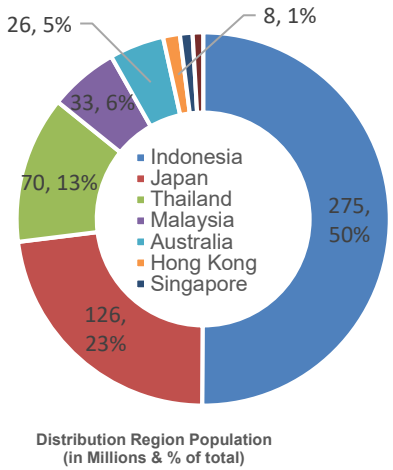
Mr Gavin Coote, Hydrix Executive Chairman, commented:

"This is particularly disappointing for Australian patients noting it is a US FDA-approved device and is being prescribed to patients in the USA.

"The FDA concluded that the Guardian is more effective at diagnosing life-threatening situations than relying on patient symptoms alone; with benefits outweighing the risks. This was affirmed by regulatory authorities in Singapore and Malaysia when they granted their approvals in 2022.

"For all the reasons we have advocated for the Guardian, we remain confident in the positive benefits the device could offer to high-risk Australian ACS patients."

The chart below shows the population of the eight countries under exclusive distribution and the regulatory status of markets other than Australia



Distribution Region Population
(in Millions & % of total)

Country / Agency	Appl. Date	Status
USA / FDA	n/a	Approved
Singapore / HSA	16-Aug-21	Approved
Malaysia / MOH	27-Dec-21	Approved
Thailand / Thai FDA	12-Oct-21	In process
New Zealand / MMDSA	11-Aug-21	WAND notified
Hong Kong	-	In process
Japan	-	In process
Indonesia	-	In planning

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Authorisation: This announcement has been authorised for release by the Board of Hydrix.

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About Hydrix Limited

Hydrix Limited (ASX: HYD) is a powerful product innovation company. Hydrix's purpose is to enhance the health, safety, and well-being of a billion lives. The company leverages its powerful product innovation capability across three business segments: Services: design, engineer and deliver world first products and innovation; Ventures: invest in high potential medtech clients; and Medical: distribute disruptive cardiovascular products.