ASX Announcement **10/12/2020**

Hydrix announces first in human trials of Phyzhon Health's PHYRARI FFR-WIRE

Key Highlights:

- First in human clinical trial of the Phyzhon PHYRARI FFR-Wire System under TGA Clinical Trial Notification scheme
- Human trial seeks to demonstrate superior performance when compared to existing devices and is anticipated to support Australian market adoption
- Trial to commence at a Melbourne-based teaching hospital in the March quarter 2021
- Potential total addressable Australian market in excess of $80 million p.a.

Hydrix Limited (ASX: HYD, '**Hydrix**' or the '**Company**') is pleased to announce a first-in-human (FIH) trial of Phyzhon Health's PHYRARI FFR-WIRE at a leading Melbourne-based teaching hospital under TGA Clinical Trial Notification (CTN) scheme.

Hydrix announced on 30 October 2020 it had secured exclusive rights to distribute the novel cardiovascular technology in Australia and New Zealand. The purpose of this human study is to demonstrate and further evaluate the efficacy and safety of the PHYRARI FFR-WIRE guidewire. The device will be used for interventional cardiology procedures on approximately 50 Australian patients. The trial is expected to commence in the March quarter of 2021.

Potential market opportunity for Hydrix

Cardiovascular disease affects 14% of the global population and is the leading cause of death.

Fractional Flow Reserve (FFR) is a technique used in coronary catheterization to measure pressure differences across a coronary artery stenosis (narrowing, usually due to atherosclerosis) to determine the amount a stenosis impedes oxygen delivery to the heart muscle (myocardial ischemia).

Current measurement of FFR can be complex to perform and not readily reproduceable, leading to a lower number of FFR procedures which could otherwise improve patient and hospital outcomes. One outcome of this human trial is to demonstrate the simple and easy-to-use handling characteristics of the PHYRARI FFR-WIRE. The primary benefit anticipated is increased safety and deployment of life-saving stents.

There are approximately 125,000 coronary angiograms performed each year in Australia leading to 60,000 Percutaneous Coronary Intervention (PCI) procedures, during which 12,000 FFR measurements are taken to determine whether to stent the artery or not.

Based on the potential benefits of the PHYRARI FFR-WIRE, Mr. Paul Kelly, Hydrix Medical - General Manager commented:

"These FIH trials are expected to demonstrate the value and ease-of-use of this technology and could hasten market adoption of the product once it launches in Australia. The proportion of coronary angiogram procedures which use the FFR technique could significantly increase, with a potential addressable market of $80 million p.a. if little more than half of all Australian coronary angiogram procedures employ FFR".

The PHYRARI FFR-WIRE is indistinguishable in mechanical and tactile performance characteristics, as well as manufacturing design, to comparable technologies commonly used today in interventional cardiology procedures. The combination of Phyzhon's coronary guidewire design and fibre optic sensing technology has the potential to transform Percutaneous Coronary Intervention (PCI) procedures.

Phyzhon will shortly submit the PHYRARI FFR-WIRE for US FDA 510K and CE approval. Once the PHYRARI FFR-WIRE is granted CE approval, Hydrix will submit an application to the TGA for approval to begin commercial sales. Hydrix Medical anticipates commercial product distribution in Australia and New Zealand commencing mid-to-late calendar year 2021.

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

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About Hydrix Limited

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