



2 March 2022

ASX ANNOUNCEMENT

Green Whistle gets the Green Light - FDA clears US Pentrox clinical trial

Medical Developments International Ltd (ASX: MVP) announces that the US Food and Drug Administration (FDA) has unconditionally lifted the agency's clinical hold on Pentrox. This means that MVP can immediately begin preparing for its Phase III US clinical trial. As anticipated, the trial will be conducted on a targeted trauma and associated pain patient group. We expect that the 2-year trial will commence recruitment in late 2022.

CEO Brent MacGregor said: "We are thrilled with this news which allows us to move forward quickly with preparations for our clinical trial. After years of hard work, our team is buoyed by the prospect of bringing the many benefits of Pentrox to the US market. This will strongly complement our growing Pentrox success in Europe, and fully supports our further investment in the product."

Chair Gordon Naylor said: "This news is important as it brings Pentrox a step closer to licensure in the US market and because the FDA is seen as a global regulatory leader. Our renewed focus on the core business continues to yield results."

Investors are invited to join a live investor presentation covering this announcement (including Q&A) on Thursday 3 March 2022 at 10am AEDT. Investors can register in advance for this presentation via the following link: https://us02web.zoom.us/webinar/register/WN_h_JHE22oQAiOoc7-7FDIQ

Authorised for release by MVP Company Secretary, Mark Edwards.

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About Pentrox®

Penthrox is a fast onset, non-opioid analgesic indicated for pain relief by self-administration in patients with trauma and those requiring analgesia for surgical procedures. Pentrox is now approved for sale in more than 40 countries and has been used safely and effectively for more than 40 years in Australia with more than 8.0 million units sold. There is growing interest in Pentrox being used in patients undergoing investigatory procedures, as well as operational procedures such as colonoscopy.

About Medical Developments International Ltd

MVP is an Australian company delivering emergency medical solutions dedicated to improving patient outcomes. MVP is a leader in emergency pain relief and respiratory products. The Company manufactures Pentrox®, a fast-acting trauma & emergency pain relief product. It is used in Australian Hospitals including Emergency Departments, Australian Ambulance Services, the Australian Defence Forces, Sports Medicine and for analgesia during short surgical procedures such as Dental and Cosmetic surgery as well as in other medical applications. MVP is expanding internationally and manufactures a range of world-leading Asthma respiratory devices.