



19 July 2019

ASX Announcement

Pentrox® USA Update

Medical Developments International Limited (ASX: MVP) advises that it met with the Food and Drug Administration (FDA) in mid-June 2019 in respect to its IND clinical hold letter issued in August 2018.

MVP now expects to be in a position to address in full, all the clinical hold issues during the first quarter of 2020.

MVP CEO, Mr. John Sharman said: "We had a good discussion with the FDA and we are clear as to what is required. Of particular importance is the willingness of the FDA to consider the recent safety data generated in Europe, and in particular the United Kingdom's Post Authorisation Safety Study. We are confident this data will prove the safety of Pentrox® to the satisfaction of the FDA and expect to submit our full response to the IND clinical hold during early 2020."

MVP can advise that as a result of the recent meeting with the FDA:

- The FDA has agreed that a requested animal study to predict idiosyncratic liver reaction to Pentrox® would not be required to be performed.
- MVP has agreed to conduct a required animal study that replicates the human dosing regimen for Pentrox®. MVP expects the study to take 6 months to complete.

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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. Penthrox has been used safely and effectively for more than 40 years in Australia with excess of 6.0 million units sold. There is growing interest in Penthrox 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 Penthrox®, 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.