

30 August 2018

ASX Announcement

Penthrox Paediatric Trial: safety update

Medical Developments International Limited (ASX: MVP) is pleased to update shareholders on the randomised, double-blind, multicentre, placebo controlled study to evaluate the safety and efficacy of methoxyflurane (PENTHROX®) for the treatment of acute pain in children and adolescents from 6 to less than 18 years of age (presenting to an Emergency Department with minor trauma).

The trial has just conducted its first scheduled Data and Safety Monitoring Board (“DSMB”) Review meeting. The DSMB is assigned to oversee the safety and progress of the trial and is a group of independent experts that are not directly involved in recruiting patients into the study, are not employees of the company and do not have any financial interest in the trials.

The DSMB considered and reported on data up to 3 August 2018:

- 2051 patients were screened, 94 were randomised of which 12 were not treated;
- Noted no serious adverse events; and
- Approved the trial to continue as planned (without modifications) to its target of 220 patients.

MVP’s CEO Mr. John Sharman said: “We are delighted the DSMB has reviewed the data to date and found Penthrox safe to continue the trial on children. Penthrox has been used safely in children in Australia and elsewhere for more than 30 years so the DSMB findings are a welcome reinforcement of our experience.”

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About PENTHROX®

PENTHROX® (methoxyflurane) is the only small, lightweight, handheld, fast-acting, inhaled analgesic that is self-administered under the supervision of the treating healthcare practitioner, indicated for the short-term relief of moderate to severe pain, associated with trauma or interventional medical procedures, in conscious adult patients. PENTHROX® provides rapid, effective pain relief in 5 minutes, with no need for needles and is not classified as an opioid. PENTHROX® allows patients to control their own pain relief by moderating the amount of PENTHROX® inhaled¹.

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. Pentrox is now approved in over 35 countries including 25 in the EU, Canada, New Zealand, South Africa and the Company expects to be selling into the majority of those countries in FY19. Locally, Pentrox continues its long-established use in Australian Hospitals including Emergency Departments, Australian Ambulance Services, the Australian Defence Force, 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.