



9 August 2016

ASX ANNOUNCEMENT

USA : Pentrox update

Medical Developments International (ASX: MVP) advises it has received a written response to its meeting request by the Food & Drug Administration (FDA) in the United States of America. On the basis of the FDA's written response, MVP has a clearer understanding of the steps required and data needed to get Pentrox approved for sale in the USA.

Amongst certain other requirements, MVP will undertake a second Phase III Pivotal Clinical Trial in the USA for "Acute Trauma Pain". We expect our USA based trial will include an appropriate mix of ethnically diversified patients.

MVP CEO, Mr. John Sharman said: "Nothing in the response received from the FDA was unexpected, which is encouraging. MVP has already successfully completed two Phase III Pivotal Clinical Trials and invested heavily in its clinical program in recent years. We have gathered sufficient clinical data to achieve the approval of Pentrox in the United Kingdom, France, Ireland, Belgium, Singapore, South Africa and elsewhere."

Mr. John Sharman said: "We are committed and confident we can do the work required and satisfy the FDA's requirements. Our advisors are working through the details of how best to gather the data needed to submit a New Drug Application to the FDA. We expect as part of that program we will have a face to face meeting with the FDA."

Mr. Sharman said: "Now that we have some clarity around the FDA's requirements, MVP will move ahead and appoint advisors to find a partner for Pentrox in the USA."

We hope to be able to update the market on a number of these developments shortly.

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About Pentrox

'Pentrox' 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' has been used safely and effectively for more than 30 years in Australia with excess of 5.0 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 minor 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.