

7 February 2017

## **ASX ANNOUNCEMENT**

### **Pentrox: European update**

Medical Developments International Limited (ASX: MVP) provides the following update on its Pentrox business in Europe.

#### **United Kingdom and Ireland**

In the United Kingdom and Ireland, Galen continue to make good progress in rolling out Pentrox. 34 Hospitals have approved and are now using Pentrox. There are 11 major trauma center hospitals in the UK, four of which have approved and are using Pentrox. Included in these major trauma centers, is St George's Hospital in London which recently approved the use of Pentrox in its Accident & Emergency department. St George's is one of the UK's largest A&E departments and is also the place where the TV program "24 hours in A&E" is filmed. In addition, formulary approval is expected from another of the UK's largest trauma centers, Royal London Hospital within the next month or so.

MVP CEO, Mr John Sharman, said "Recent success in the major trauma centers in the UK and Ireland is very encouraging and the feedback from the market is very positive. We expect a number of additional Hospitals and Ambulance Trusts to approve Pentrox in the coming months."

#### **Rest of Europe**

The application to have Pentrox approved for sale in 22 additional European countries was submitted to the United Kingdom's Medicine & Healthcare products Regulatory Agency (MHRA) under the decentralised procedure in November 2016. MVP expects approvals to sell Pentrox in these 22 countries and another 15 countries via the National Approval process during the course of 2017 and 2018.

## Clinical Development Program

MVP's clinical development program in Europe is progressing well.

- MVP's Paediatric trial which is planned for 10 sites across the United Kingdom and Ireland is expected to enroll its first patient by July 2017. This trial adds to the paediatric data base gathered in MVP's Pivotal Phase III "STOP" study and we anticipate the data collected will be used to expand the indication for Pentrox into the paediatric population in Europe and in other markets around the world. The trial results should also be available to support MVP's application to have Pentrox approved in the USA.
- MVP's Post Authorisation Safety Study in the UK enrolled its first patient during Q2FY17. The study tracks patients after using Pentrox. The data collected will deliver important safety data which will be used to support additional Pentrox approvals globally.
- Together with Mundipharma in Europe, MVP is developing a clinical trial program to extend the indications for use of Pentrox into Surgical Procedures. We expect this Pivotal Phase III study protocol to be enrolling patients during 2018 and to achieve this second indication for Pentrox in Europe during 2019.

Mr Sharman said: "We are very excited about our clinical development program in Europe. Our focus is on extending the use of Pentrox in markets around the world and the data generated from these trials will play an important role in the future growth of Pentrox globally."

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### **About Pentrox**

Penthrox is a fast onset, non-opioid analgesic which is indicated in Australia 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 30 years in Australia with excess of 5 million units sold. Mundipharma International has exclusive product rights in 39 European markets (including France, Germany, Italy and Spain, but excluding Hungary, Republic of Ireland and the United Kingdom).

### **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.