



Mundipharma announces positive outcome of the European Decentralised Procedure (DCP) for Pentrox® (methoxyflurane) for emergency relief of moderate to severe pain

Cambridge, 11 December 2017 – The Mundipharma network of independent associated companies announces today the positive outcome of the European Decentralised Procedure (DCP) for Pentrox® (methoxyflurane) in 22 European countries for the emergency relief of moderate to severe pain in conscious adult patients with trauma and associated pain.¹

Penthrox is a non-opioid based drug-device combination that consists of a small green inhaler and a 3 ml vial of methoxyflurane.¹ The median time to first pain relief was 5 minutes or 6-10 inhalations² and it can be self-administered by conscious patients under supervision by someone trained in its administration.¹

In Europe, pain remains undertreated in both the emergency department and pre-hospital setting where the prevalence of pain can be up to 90%³⁻⁶ and 70%,⁷ respectively. Pain negatively impacts the physical and psychological well-being of patients, causes stress and reduces patient satisfaction with their treatment.^{8,9}

“Pain is hugely prevalent and very often undertreated in pre-hospital settings and emergency departments,” said Professor Karim Tazarourte, Chief of Emergency Medicine at Edouard Herriot Hospital, Lyon, France, and Vice President of the French Society of Emergency Medicine (SFMU). *“This ongoing reality represents a significant barrier to correctly managing patients, in their transport to and within a healthcare centre as well as when making a medical diagnosis. As a healthcare provider, one of our principal goals should be to help the patient manage and take charge of their pain.”*

Christian Mazzi, Chief Commercial Officer at Mundipharma, commented, *“This marketing authorisation is a major step towards bringing Pentrox, a new, non-opioid based therapeutic, to patients throughout Europe. We’re delighted to be able to continue our proud heritage as leaders in pain management with this treatment and we look forward to working with the different reimbursement bodies to make sure patients and hospitals have access to it as soon as possible.”*

The current DCP outcome approves the use of the treatment in Austria, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Germany, Iceland, Italy, Latvia, Lithuania, Luxembourg, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden. It was approved for use in Belgium and France in June 2016.



Penthrox has been extensively used for over 40 years in Australia and New Zealand,¹⁰ with more than 5 million administrations.¹¹ It has an established tolerability profile and a body of supporting evidence in adult trauma pain.^{12,13} Adverse events related to treatment, such as dizziness and headaches, are mild and transient.²

-Ends-

Notes to editors:

- Nephrotoxicity (kidney damage) has been associated with historic use of high-dose methoxyflurane for anaesthesia¹⁰ and therefore the recommended dose should not be exceeded¹
- Methoxyflurane is no longer available as an anaesthetic, only as a low-dose analgesic¹⁰
- A large observational study of 135,770 patients (which included 17,629 patients who received Pentrox), showed no link between the treatment and kidney disease following administration¹⁴

About Pentrox

Penthrox (methoxyflurane) is a non-narcotic, self-inhaled analgesic for the emergency relief of moderate to severe pain in conscious adult patients with trauma and associated pain.¹ It is currently marketed in 18 countries around the world including: Australia, New Zealand, UK, Ireland, France, Belgium, Mexico, Singapore, Taiwan and South Africa. It is also in the process of being submitted to authorities in Hong Kong, Iran, Israel, Malaysia, Russia, Saudi Arabia and others.

The Mundipharma network of independent associated companies has exclusive rights to Pentrox in 40 European markets, including France, Germany, Italy and Spain, but excluding Republic of Ireland and the United Kingdom.

About the Mundipharma network

The Mundipharma global network of privately-owned independent associated companies was founded in 1956 by doctors, and now operates in over 120 countries worldwide. We are focused on developing business partnerships to identify and accelerate meaningful technology across an increasingly diverse portfolio of therapy areas including respiratory, oncology, pain, and biosimilars. Consistent with our entrepreneurial heritage, we like to think we see what others don't by challenging conventional wisdom and asking different and challenging questions. By working in partnership with all our stakeholders, the Mundipharma network develops medicines that create value for patients, payers and wider healthcare systems.

For more information please visit: www.mundipharma.com.



For further information please contact:

Kristine Kelly
Mundipharma
Kristine.kelly@mundipharma.com
Tel: 44 (0) 7976 288555

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