

FOR EUROPEAN MEDICAL AND TRADE MEDIA ONLY

FOR IMMEDIATE RELEASE

Mountain rescue study launches to investigate use of Pentrox[®] (methoxyflurane) for trauma-related pain in hostile environments

- Study will enrol 200 adult patients with limb trauma who are rescued by helicopter
- Efficacy, tolerability and practicality of use of the inhaled analgesic in hostile mountain environments to be investigated

Cambridge, UK, 27 March 2019

The Mundipharma network of independent associated companies announced today that the first patient has been enrolled into a new study investigating the efficacy of Pentrox[®] ▼ (methoxyflurane, MEOF) in conscious, stable adult patients with moderate-to-severe trauma-related pain rescued from hostile, mountainous areas.¹ The METEORA trial is a Phase IIIb, prospective, single-arm, multicentre trial in 200 adult patients with limb trauma who are rescued by the Helicopter Emergency Medical Service (HEMS) in Italy.¹

The trial will assess the reduction in pain intensity (using the visual analogue scale [VAS] 0-100 mm) for patients treated with inhaled MEOF; and whether additional pain-relieving medication is needed.¹ The practicality of MEOF use in an emergency rescue situation, patient satisfaction and any adverse events will also be evaluated.¹ The primary endpoint is the percentage of patients achieving at least 30% improvement in VAS pain intensity within the first 10 minutes of MEOF administration.¹

Lead Investigator, Professor Franco Marinangeli commented: *“In emergency rescue situations rapid, effective pain relief is vital. Not only does it reduce the patients’ stress and discomfort, it can also make it easier to assess, treat and transport them. Research shows that under-treatment of trauma pain in the pre-hospital emergency setting remains a significant problem. I am pleased to be leading this study into the use of Pentrox in this new setting.”*

Antonella Sblendido, Medical Advisor, Mundipharma added: *“Pentrox has been widely used by Ambulance services in Australia since 1975 and is now approved in Europe for the emergency relief of moderate to severe trauma-related pain in conscious adults. Given its portability, ease of use and rapid onset, we felt it was important to investigate its use in hostile environments, where more pain-relief options are needed.”*



FOR EUROPEAN MEDICAL AND TRADE MEDIA ONLY

Giovanni Sbrana, Principal Investigator, Grosseto Helicopter Emergency Medical Service said: “We are excited to be involved in the study and to have enrolled the first patient. Our Helicopter Service operates in a rural area in Tuscany with a very low-density population where we perform more than 1,000 rescue missions a year. Helicopter is the only way to reach some patients and to give them lifesaving therapies and pain relief. As was the case with our first METEORA patient, we often have to deal with challenging weather conditions which means that we need to stabilise the patient quickly and remove them in order to avoid a helicopter becoming unavailable. Therefore we need a treatment with fast onset and convenient administration, and we look forward to seeing the results as the study progresses.”

To find out more about the study visit: <https://link.springer.com/article/10.1007/s12325-018-0816-8>

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get to your local medicines regulatory authority.

-Ends-

Notes to editors:

About Pentrox® (methoxyflurane, MEOF)

Penthrox is a small, light-weight, hand-held, inhaled non-opioid analgesic.² It is indicated in Europe for the emergency relief of moderate to severe pain in conscious adults with trauma and associated pain.^{3,4} It is a self-administered analgesic (under supervision) and provides rapid pain relief within five minutes or six to ten inhalations.^{2,3,5} MEOF has been extensively used for 40 years in Australia and New Zealand, with more than six million administrations, including use by Australian air ambulance services.^{1,6} It has an established tolerability profile and a body of supporting evidence in adult trauma pain.^{7,8}

Mundipharma International Corporation Limited has exclusive rights to Pentrox in 40 European markets, including France, Germany, Italy and Spain, but excluding Republic of Ireland and the United Kingdom.

PENTHROX® is a registered trade mark of Medical Developments International Limited and is used under licence.



FOR EUROPEAN MEDICAL AND TRADE MEDIA ONLY

About the METEORA Study¹

METEORA is a Phase IIIb, prospective, single-arm, multicentre trial conducted from approximately 11 helicopter rescue bases in Italy (a pre-hospital setting). It will study approximately 200 adult patients with minor trauma to the limbs (e.g. fracture or dislocation) and a pain score of at least 4 on the numerical rating scale (NRS) who are rescued from hostile, mountainous areas by HEMS. Patients will receive up to 2 x 3 mL MEOF, self-administered by inhalation under medical supervision, with rescue medication permitted. Pain intensity will be measured using a 100-mm VAS and NRS at specified timepoints.

About Management of Trauma Pain in the Pre-Hospital Setting

Trauma pain requires fast, effective pain relief (analgesia) and in an emergency rescue setting this can reduce a patient's stress and discomfort making it easier to assess, treat and move them.¹

Inadequate pain treatment can cause clinical deterioration, yet pain is undertreated in both the emergency department and pre-hospital setting and remains a significant problem.^{1,9-13} Current analgesics have limitations in pre-hospital settings and there is a need for fast-acting, non-invasive, non-narcotic analgesia.^{1,14}

About the Mundipharma network

Mundipharma is a global network of privately-owned independent associated companies whose purpose is to move medicine forward.

With a high performing and learning organization that strives for innovation and commercial excellence through partnerships, we successfully transformed and diversified our European portfolio of medicines to create value for patients, payers and wider healthcare systems across important therapeutic areas such as Diabetes, Respiratory, Oncology, Pain and Biosimilars.

Contact:

Tiffany Fretwell
Communications Lead, Mundipharma
Tiffany.fretwell@mundipharma.com
+44 (0) 1223 393 361

Eleanor Craven
Makara Health

FOR EUROPEAN MEDICAL AND TRADE MEDIA ONLY

eleanor@makarahealth.com

Tel: +44 (0) 2381 247 327

References

- 1 Marinangeli F, et al. *Adv Ther* 2018;35:2081.
- 2 Coffey F, et al. *Emerg Med J* 2014;31:613-8.
- 3 Pentrox UK Summary of Product Characteristics. Available at: <https://www.medicines.org.uk/emc/product/1939/smpc> Last accessed: January 2019.
- 4 Medical Developments international. ASX Announcement: Pentrox approved in another 22 European countries. 2017. Available from: <https://www.medicaldev.com/news/asx-announcement-pentrox-approved-another-22-european-countries/> Last accessed: January 2019.
- 5 Coffey F, et al. *Adv Ther* 2016;33:2012-31.
- 6 Porter KM, et al. *Open Access Emerg Med* 2018;10:149-164.
- 7 Grindlay J, Babi FE. *Emerg Med Australas* 2009;21(1):4-11.
- 8 Jephcott C, et al. *Br J Anaesth* 2018;120(5):1040-8.
- 9 Berben SA, et al. *Injury* 2008;39:578-85.
- 10 Boccard E, et al. *Ann Fr Med Urgence* 2011;1:312-9.
- 11 Gueant S, et al. *Eur J Anaesthesiol* 2011;28:97-105.
- 12 Berben SA, et al. *Clin J Pain* 2011;27:587-92.
- 13 Cordell WH, et al. *Am J Emerg Med* 2002;20:165-9.
- 14 Sinatra R. *Pain Med* 2010;11:1859-71.