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Mundipharma receives CHMP positive opinion for Nyxoid® (intranasal naloxone spray)

- Nyxoid® (intranasal naloxone spray) set to be the first pan-EU intranasal formulation available for the reversal of opioid overdose
- Novel formulation designed to support take-home naloxone programmes and provide 'first responders' with a needle-free option

Cambridge, UK, 15TH September 2017 – Mundipharma today announce that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion for Nyxoid® (intranasal naloxone 1.8 mg)[i] for use in the emergency reversal of opioid overdose. If approved, this will be the first intranasal formulation of naloxone to receive a pan-EU approval. The European Commission will now review the CHMP opinion and a final decision is expected in Q4 2017.

Opioid-induced death represents a significant public health problem responsible for 82 per cent of fatal drug overdoses in the EU, the majority of which are associated with heroin.[ii] Naloxone has been used in routine practice to reverse the effects of opioid overdose for more than 40 years, and is included in the World Health Organization (WHO) Model List of Essential Medicines.[iii] Mundipharma has developed an intranasal formulation to provide potential 'first responders' in overdose situations with an easy to use, needle-free option that is suitable for use in a take-home naloxone setting.

Rachel Gooch, Head of Addiction Therapy, at Mundipharma International Limited, said: "This positive opinion is a significant step for Mundipharma and we look forward to the final European Commission decision in Q4 2017. For many years naloxone has been a cornerstone of the emergency reversal of opioid overdose, however it must be delivered rapidly in order to preserve life. We know that a longer period between overdose and the arrival of emergency services can lead to a greater risk of severe damage or death. [iv] We therefore expect the availability of an easy to use, needle-free option, suitable for use in take home setting, to be a welcome additional treatment option with potential to reduce the overall number of opioid-related overdose deaths in Europe."

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Mundipharma's submission for approval for Nyxoid is based on data from a 5 part, single site, open label, randomised, single dose, crossover study involving 38 healthy volunteers. It is anticipated that Nyxoid (1.8 mg naloxone) will deliver therapeutic concentrations comparable with an IM dose of 0.4 mg, currently regarded as the standard of care in the event of opioid overdose.[v] The product is well tolerated with a similar side-effect profile to that of injectable naloxone.[vi]

* Nyxoid contains 1.8 mg naloxone, which is equivalent to 2 mg naloxone hydrochloride.

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Notes to editors:

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

About Nyxoid®

Naloxone has been used in routine practice to reverse the effects of opioid overdose for more than 40 years, and is included in the WHO List of Essential Medicines.[iii] Nyxoid® (intranasal naloxone 1.8 mg in 0.1 ml)[i] has been developed by Mundipharma as an intranasal formulation in order to provide potential 'first responders' in overdose situations with an easy to use, needle-free option suitable for use in a take-home naloxone setting. Take-home programmes are intended to increase the availability of naloxone in places where overdoses are most likely to occur, and provide prompt, potentially life-saving treatment.[ii],[vii]

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References:

[i] Mundipharma Data on file: ADD-10003
[ii] European Monitoring Centre for Drugs and Drug Addiction (2017), European Drug Report 2017. Available online via: http://www.emcdda.europa.eu/system/files/publications/4541/TDAT17001ENN.pdf
[iii] World Health Organization (2017) 20th WHO Model List of Essential Medicines
[iv] European Monitoring Centre for Drugs and Drugs Addiction (2016) Preventing opioid overdose deaths with take-home naloxone
[v] Mundipharma Research Limited (2016) Data on file: ADD-10002
[vi] Mundipharma (2017) Annex 1: Summary of Product Characteristics Nyxoid
[vii] World Health Organization (2014) Community management of opioid overdose

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