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Press Release

Hikma announces exclusive commercial partnership with Emergent BioSolutions for KLOXXADO® (naloxone HCl) nasal spray 8 mg

London, 14 January 2025 – Hikma Pharmaceuticals PLC (Hikma), the multinational pharmaceutical group, today announces that it has entered an exclusive commercial partnership with Emergent BioSolutions (Emergent) for the sale of KLOXXADO® naloxone HCl nasal spray 8 mg in the U.S. and Canada. KLOXXADO® was approved by the US Food and Drug Administration (FDA) in April 2021 for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression, for adult and pediatric patients. Emergent distributes NARCAN® Nasal Spray 4 mg, which is the first FDA-approved over-the-counter naloxone product for the emergency treatment of opioid overdose.

Under the terms of the six-year agreement, Emergent will add KLOXXADO® Nasal Spray to its naloxone product portfolio and will be responsible for all North America product sales and marketing. Hikma will continue producing its 8 mg naloxone HCl nasal spray in its Columbus, Ohio manufacturing facility and will provide it to Emergent as its exclusive commercial partner.

“We are thrilled to be partnering with Emergent, who have deep experience in getting lifesaving naloxone nasal spray into the hands of those who can use it to help save lives,” said Hafrun Fridriksdottir, President of Hikma’s Generics business. “This partnership combines Hikma’s excellent nasal spray manufacturing capabilities with Emergent’s well-established naloxone HCl nasal spray commercial expertise and strong stakeholder engagement. Hikma remains committed to ensuring that all forms of naloxone we produce – KLOXXADO® Nasal Spray, as well as the injectable vials and prefilled syringes that we will continue to manufacture and market – are widely accessible to all who can benefit from them, including patients, friends, family members and the public health community.”

About Naloxone
Naloxone hydrochloride is a medicine that rapidly reverses an opioid overdose. It can quickly restore normal breathing in someone experiencing an opioid overdose and should be given to any person who shows signs of an opioid overdose or when an opioid overdose is suspected.

KLOXXADO® is indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression, for adult and pediatric patients.[1] KLOXXADO® is not a substitute for emergency medical care.[1] KLOXXADO® is intended for immediate administration as emergency therapy in settings where opioids may be present.

[1] - https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=ebf0f833-c1c0-487c-8f29-01fa8c61b6cb&type=display

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About Hikma
Hikma Pharmaceuticals PLC (LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY)
(LEI:549300BNS685UXH4JI75) (rated BBB-/stable S&P and BBB-/positive Fitch)

Hikma helps put better health within reach every day for millions of people around the world. For more than 45 years, we've been creating high-quality medicines and making them accessible to the people who need them. Headquartered in the UK, we are a global company with a local presence across North America, the Middle East, and North Africa (MENA) and Europe, and we use our unique insight and expertise to transform cutting-edge science into innovative solutions that transform people's lives. We're committed to our customers, and the people they care for, and by thinking creatively and acting practically, we provide them with a broad range of branded and non-branded generic medicines. Together, our 9,100 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner, and through our venture capital arm, are helping bring innovative health technologies to people around the world. For more information, please visit: www.hikma.com

Important Safety Information for KLOXXADO® (naloxone HCl) Nasal Spray 8 mg
Contraindications
Hypersensitivity to naloxone hydrochloride or to any of the other ingredients

Warnings and Precautions

- Use KLOXXADO® right away if you suspect an opioid overdose emergency, even if you are not sure, because an opioid overdose emergency can cause severe injury or death. Signs and symptoms of an opioid overdose emergency may include:
  - Unusual sleepiness; you are not able to awaken the person with a loud voice or by rubbing firmly on the middle of their chest (sternum).
  - Breathing problems, including slow or shallow breathing in someone difficult to awaken or who looks like they are not breathing.
  - The black circle in the center of the colored part of the eye (pupil) is very small (sometimes called "pinpoint pupils") in someone difficult to awaken.
- Family members, caregivers or other people who may have to use KLOXXADO® in an opioid overdose emergency should know where KLOXXADO® is stored and how to give KLOXXADO® before an opioid overdose emergency happens.
- **Get emergency medical help right away after using the first dose of KLOXXADO®.** Rescue breathing or CPR (cardiopulmonary resuscitation) may be needed while waiting for emergency medical help.
- The signs and symptoms of an opioid overdose emergency can return after KLOXXADO® is given. If this happens, give another dose after 2 to 3 minutes, using a new KLOXXADO® device, alternating nostrils, and watch the person closely until emergency medical help arrives.
- Do not use KLOXXADO® if you are allergic to naloxone hydrochloride or any of the ingredients in KLOXXADO®.

- KLOXXADO® can cause sudden and severe opioid withdrawal, the symptoms of which may include body aches, diarrhea, increased heart rate, fever, runny nose, sneezing, goosebumps, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, stomach cramps, weakness and increased blood pressure.
- In infants under 4 weeks old who have been receiving opioids regularly, sudden opioid withdrawal may be life-threatening if not treated the right way. Signs and symptoms include: seizures, crying more than usual, and increased reflexes.
- Tell your doctor about all of your medical conditions before using KLOXXADO®, including if you have heart problems, are pregnant or plan to become pregnant, are breastfeeding or plan to breastfeed.
- Tell your doctor about all of the medicines you take, including prescription and over-the-counter medicines, drugs, vitamins and herbal supplements.

Side Effects
The following serious side effect is discussed in the full Prescribing Information for KLOXXADO®:

- Sudden and Severe Opioid Withdrawal

Symptoms of sudden and severe opioid withdrawal resulting from the use of KLOXXADO® in someone regularly using opioids include: body aches, diarrhea, increased heart rate, fever, runny nose, sneezing, goosebumps, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, stomach cramps, weakness and increased blood pressure.
Infants may have seizures, cry more than normal and have increased reflexes.
Some people may become aggressive after abrupt reversal of opioid overdose.
In two clinical studies, a total of 47 healthy adult volunteers were exposed to a single dose of KLOXXADO®, one spray in one nostril. Side effects were reported in two subjects for each of the following: abdominal pain, asthenia, dizziness, headache, nasal discomfort, and presyncope.
These are not all of the possible side effects of KLOXXADO®. Contact your doctor for medical advice about side effects.

Pregnancy, Infancy and Breastfeeding, Children
Tell your doctor if you are pregnant or plan to become pregnant. If you are pregnant and opioid dependent, use of KLOXXADO® may cause withdrawal symptoms in you and your unborn baby. A healthcare provider should monitor you and your unborn baby right away after you use KLOXXADO®.
There is no information regarding the presence of naloxone in human milk, the effects of naloxone on the breastfed infant or on milk production.
If the primary concern is an infant at risk of an overdose, consider whether other naloxone-containing products may be more appropriate.
KLOXXADO® nasal spray is safe and effective in children for known or suspected opioid overdose.

Dosage and Administration
Do not attempt to prime or test-fire the device. Each KLOXXADO® Nasal Spray contains only 1 dose of medicine and cannot be reused. Read the "instructions for use" at the end of the Prescribing Information and Medication Guide for detailed information about the right way to use KLOXXADO® Nasal Spray.

Storage and Handling
Store KLOXXADO® at room temperature between 68°F to 77°F (20°C to 25°C). Do not expose to temperatures below 41°F (5°C) or above 104°F (40°C). Do not freeze KLOXXADO®. Keep KLOXXADO® in its box until ready to use. Protect from light. Replace KLOXXADO® before the expiration date on the box. Keep KLOXXADO® and all medicines out of the reach of children.

For more information, please see the full Prescribing Information and Medication Guide, which you can find on our website at www.kloxxado.com.

- To report an adverse event or product complaint, please contact us at us.hikma@primevigilance.com or call 1-877-845-0689 or 1-800-962-8364.
- Adverse events may also be reported to the FDA directly at 1-800-FDA-1088 or www.fda.gov/medwatch.

About NARCAN® Nasal Spray
NARCAN® Naloxone HCl Nasal Spray 4 mg is the first FDA-approved, over-the-counter (OTC) 4 mg naloxone product for the emergency treatment of opioid overdose. NARCAN® Nasal Spray is not a substitute for emergency medical care. Repeat dosing may be necessary. Use as directed.

Distributed by: Hikma Specialty USA Inc., Columbus, OH 43228.

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