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Press Release

Hikma Pharmaceuticals reaffirms commitment to expanding access to overdose-reversal medicine naloxone at White House meeting

London 6 June 2024 – Hikma Pharmaceuticals in the US this week reaffirmed its longstanding commitment to expanding access to the opioid overdose-reversal medicine naloxone while participating with the Office of National Drug Control Policy (ONDCP) in a White House conversation on opioid reversal agents.

ONDCP convened the June 4th White House meeting for an important pharmaceutical-industry dialogue about FDA-approved overdose prevention antagonists, including naloxone, and manufacturers' critical role in expanding access to these medicines. This meeting follows ONDCP Director Dr. Rahul Gupta's visit to Hikma's manufacturing facility in Columbus, Ohio earlier this year. While visiting with Hikma, Dr. Gupta witnessed the production of naloxone and met with local harm reduction groups to learn about Hikma's partnerships, donation programs and other efforts to address the opioid epidemic.

"As a manufacturer of multiple forms of opioid reversal agents, Hikma continues taking action to help address the opioid overdose epidemic," said Dr. Hafrun Fridriksdottir, President of Hikma's Generics business. "We are partnering with health care providers, non-profit organizations and the public health community to ensure naloxone is widely accessible to all who can benefit from it, including by donating more than 450,000 doses of naloxone over the last three years. We were honored to join Dr. Gupta, his colleagues and industry peers at the White House for this important conversation to advance our shared goal of saving lives through expanding access to overdose-reversal medicines like naloxone."

Hikma has a decades-long record of manufacturing and supplying naloxone and opioid use disorder (OUD) medicines. The company manufactures multiple forms and delivery methods of naloxone including generic injectable vials and prefilled syringes, and KLOXXADO® (naloxone 8mg) intranasal spray.

Through its Hikma Community Health initiative, Hikma is partnering with those on the frontlines of the opioid public health emergency across the US to help expand access to naloxone, including by:

- Donating more than 450,000 doses of KLOXXADO® and injectable naloxone to harm reduction groups, community organizations and others across the US. With the help of more than 40 donation partners, KLOXXADO® has been distributed for free in places it can have the biggest impact, including music festivals, downtowns and schools.

- Donating 50,000 vials of injectable naloxone in 2021 to members of Remedy Alliance – a leading supplier of naloxone to harm-reduction programs in the US – to help ease a nationwide shortage.

- Furthering our partnership with Remedy Alliance by providing the first and only private label, discounted naloxone injectable medicine made specifically for the harm-reduction community. As covered in The Washington Post, this partnership ensures supply and price are no longer barriers to this opioid overdose antidote to hundreds of harm reduction groups nationwide.

- Ensuring widespread access to KLOXXADO® by providing a Co-Pay Assistance Program for eligible individuals, further increasing access and decreasing out-of-pocket costs to this life-saving medication.

- Partnering with State Government and Community Programs to expand access to our naloxone portfolio and continuing to provide generic medications for the treatment of substance use disorder to patients and health care providers.

-- ENDS --

This product has been approved for marketing in the United States by the US FDA. This product approval does not confer the right on Hikma, or any other party, to market this product outside the United States.

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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 About 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.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit https://www.fda.gov/medwatch or call 1-800-FDA-1088.

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