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Press Release

Hikma hosts White House Drug Policy Director Dr. Rahul Gupta at its Columbus, Ohio manufacturing facility

Continues Hikma and the Office of National Drug Control Policy effort to combat the opioid overdose epidemic in the US

Columbus, OH – Feb. 21, 2024 – Hikma Pharmaceuticals PLC (Hikma), the multinational pharmaceutical company, today welcomed Dr. Rahul Gupta, Director of the White House Office of National Drug Control Policy (ONDCP), to its Columbus, Ohio manufacturing facility for a visit and important dialogue on the US opioid overdose epidemic and Hikma's and ONDCP's shared goal of expanding the availability and awareness of life-saving naloxone.

During the visit, Dr. Gupta met with Hikma employees and toured the Columbus facility, observing firsthand the production of Hikma's overdose reversal medicine KLOXXADO® (naloxone HCl) nasal spray 8mg. Following the tour, Dr. Gupta and Hikma's leadership held a roundtable with members of two Ohio-based harm reduction organizations to discuss the ongoing opioid epidemic and how industry, government, community organizations and others can work together to meet the urgent needs of US patients and communities.

"In his Unity Agenda, President Biden set a clear directive: we must all come together to address the nation's overdose epidemic," said White House Office of National Drug Control Policy (ONDCP) Director Dr. Rahul Gupta. "Not only are we working closely across federal agencies, but with partners at the state, local, and community levels to save lives and ensure everyone has the resources they need to stay healthy and thrive. Expanding access to overdose reversal medication like naloxone is a key priority of this Administration, and we will continue doing all we can to get this lifesaving tool in communities throughout the country."

"We were honored to host Dr. Gupta at our Columbus facility for this important visit to advance our shared goal of saving lives through expanding access to overdose-reversal medicines like naloxone," said Brian Hoffmann, President, Generics, Hikma. "Hikma firmly believes that no one who needs overdose reversal medicine should lack access because of costs, awareness or availability. That's why Hikma is proud to manufacture all forms of naloxone including generic sterile injectable and pre-filled syringe formulations, in addition to KLOXXADO®. We are committed to continuing to work with Dr. Gupta and his colleagues, health care providers, non-profit organizations and the public health community to ensure naloxone is widely accessible to all who can benefit from it."

"We were grateful to have participated in today's important conversation about how government and industry can work together with the harm reduction community to address the ongoing opioid epidemic," said Kelsey Caitlin Bates, Black Community Strategy Director and Regional Coordinator, Harm Reduction Ohio. "Driven by a commitment to science, compassion, and human rights, we advocate for the autonomy of choice, empowering individuals to navigate their health decisions, including naloxone use, in alignment with their values and needs."

As the US FDA, ONDCP and others have noted, naloxone is a critical tool for individuals, families, first responders and communities to help reduce opioid overdose deaths, and expanding access to all forms of naloxone is one of the top ways to address the overdose crisis.

Hikma manufactures multiple formulations of naloxone and has been working with communities across the US for more than 20 years to provide medicines that help people recover from opioid use disorder. Through its Hikma Community Health™ initiative, it has partnered with US non-profits and harm reduction organizations to help expand access to its entire naloxone portfolio.

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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.

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