Emergent BioSolutions Gains Exclusive Commercial Rights to KLOXXADO® (naloxone HCl) Nasal Spray from Hikma Pharmaceuticals

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- Alongside over-the-counter NARCAN® Nasal Spray 4 mg, prescription KLOXXADO® (naloxone HCl) Nasal Spray 8 mg will expand Emergent's ability to distribute multiple life-saving opioid overdose emergency treatments to patients, customers and communities in need
- Focus remains on increasing access, raising awareness and ensuring strong supply to meet the ongoing demand of naloxone nasal spray

GAITHERSBURG, Md., Jan. 14, 2025 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE: EBS) announced today that it has entered into an agreement to obtain exclusive commercial rights in the U.S. and Canada to Hikma Pharmaceuticals' KLOXXADO ® (naloxone HCl) Nasal Spray, an 8 mg naloxone agent that is approved for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.[1] This six-year agreement complements and strengthens Emergent's mission to protect, enhance, and save lives by helping to reduce opioid overdose deaths —providing compelling product options, combined with a commitment to increasing naloxone access, awareness, and education.

There have been great strides in the fight against the opioid epidemic since 2018 when Emergent first acquired its flagship product, NARCAN® Nasal Spray, which is designed to rapidly reverse the effects of a life-threatening opioid emergency.[2] A recent report from the Centers for Disease Control and Prevention confirms the number of opioid overdose deaths in the U.S. decreased last year – the first meaningful decline since 2018.[3] There are a variety of factors that contributed to this decline; and such progress reinforces the positive impact of Emergent's comprehensive national strategy and ongoing efforts to increase access to and awareness of available naloxone nasal spray.

"The initial signs of progress toward stemming the tide of lives lost to opioid overdose are promising. Emergent's relentless dedication to working with those on the frontlines of the epidemic, speaking with families and caregivers, and engaging with advocates and other critical stakeholders in the fight, underscores that even one death is too many and our commitment to doing what we can to help remains steadfast," said Joe Papa, president and chief executive officer, Emergent. "Meeting the needs of our patients and customers by now offering two nasal naloxone products at different strengths – NARCAN® Nasal Spray 4 mg and KLOXXADO® Nasal Spray 8 mg – allows Emergent to do its part to help save lives from this devastating crisis."

Distributing both NARCAN® Nasal Spray 4 mg and KLOXXADO® Nasal Spray 8 mg through Emergent's expansive distribution networks will provide federal and state leaders, community-based organizations, harm reduction groups, law enforcement and first responders with the flexibility to tailor their approach to opioid overdose reversal treatment for specific patients and communities. NARCAN® Nasal Spray is widely available nationwide over the counter and will continue to be a trusted 4 mg naloxone standard of care in the community setting. With its 8 mg dosage, KLOXXADO® Nasal Spray is a prescription option for those who choose to administer a higher dose of naloxone.

"In the midst of responding to an opioid overdose, having access to safe and effective naloxone treatment is paramount, and NARCAN ® Nasal Spray 4 mg and KLOXXADO® Nasal Spray 8 mg are proven tools to help reverse the effects of an opioid overdose," said Dr. Simon Lowry, chief medical officer, Emergent. "Broadening public awareness and expanding access to life-saving naloxone, the current standard of care for opioid overdose reversal, is critical for anyone who may be impacted by the opioid epidemic."

Under the terms of the agreement, Hikma will continue to manufacture KLOXXADO® Nasal Spray 8 mg to maintain distribution and availability. KLOXXADO® Nasal Spray will soon be integrated into Emergent's proprietary NARCANDirect™ online distribution network where qualified direct purchasers, such as emergency medical services, law enforcement, fire departments, government agencies, schools/universities, and community-based naloxone distribution programs, can purchase and ship bulk quantities.

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.

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.

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About Emergent BioSolutions
At Emergent, our mission is to protect and enhance life. For over 25 years, we've been at work defending people from things we hope will never

happen—so we are prepared just in case they ever do. We provide solutions for complex and urgent public health threats through a portfolio of vaccines and therapeutics that we develop and manufacture for governments and consumers. We also offer a range of integrated contract development and manufacturing services for pharmaceutical and biotechnology customers. To learn more about how we plan to protect or enhance 1 billion lives by 2030, visit our website and follow us on LinkedIn, X, Instagram, Apple Podcasts and Spotify.

Safe Harbor Statement

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical fact, are forward-looking statements. We generally identify forward-looking statements by using words like "anticipate," "believe," "continue," "could," "estimate," "expect," "forecast," "future," "goal," "intend," "may," "plan," "position," "possible," "potential," "predict," "project," "should," "target," "will," "would," and similar expressions or variations thereof, or the negative thereof, but these terms are not the exclusive means of identifying such statements. Forward-looking statements are based on our current intentions, beliefs and expectations regarding future events based on information that is currently available. We cannot guarantee that any forward-looking statements will be accurate. Readers should realize that if underlying assumptions prove inaccurate or if known or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. Readers are, therefore, cautioned not to place undue reliance on any forward-looking statements. Any forward-looking statement speaks only as of the date of this press release, and, except as required by law, we do not undertake any obligation to update any forward-looking statement to reflect new information, events or circumstances.

There are a number of important factors that could cause the company's actual results to differ materially from those indicated by any forward-looking statements. Readers should consider this cautionary statement, as well as the risk factors and other disclosures included in our periodic reports filed with the U.S. Securities and Exchange Commission, when evaluating our forward-looking statements.

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[1]KLOXXADO® (Naloxone HCl) Nasal Spray [prescribing information]. Columbus, OH: Hikma Specialty USA, Inc.; 2021

[2] NARCAN® Nasal Spray [drug facts label]. Plymouth Meeting, PA: Emergent Devices; 2023

[3] Centers for Disease Control and Prevention. Provisional Drug Overdose Death Counts. Updated May 15, 2024. https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

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Source: Emergent BioSolutions