Emergent BioSolutions Marks 10-Year Anniversary of the U.S. FDA Approval of NARCAN® Nasal Spray and Reinforces its Commitment to Increasing Naloxone Access

November 18, 2025

GAITHERSBURG, Md., Nov. 18, 2025 (GLOBE NEWSWIRE) -- Today Emergent BioSolutions (NYSE: EBS) recognizes the 10-year anniversary of the U.S. Food and Drug Administration (FDA) approval of NARCAN® (naloxone HCl) Nasal Spray as the first FDA-approved nasal naloxone spray for emergency treatment of opioid overdose. This historic approval made the life-saving medication easy to administer in both medical and community settings, ultimately leading to NARCAN® Nasal Spray becoming the first FDA-approved, over-the-counter (OTC) 4 mg naloxone product in 2023.

"When I lost both of my sons to opioid overdoses, I came face to face with the irreversible and devastating toll of this crisis, but through my advocacy and educational efforts, I have also witnessed the tremendous progress that has been made," said Dr. Bonnie Milas, clinical professor of anesthesiology and critical care medicine at the University of Pennsylvania. "NARCAN® Nasal Spray has had a profound impact on outcomes over the past 10 years by making it easier for first responders, families and community members to respond in the event of an opioid overdose emergency, giving people a second chance at life."

Naloxone has a long history of safe and effective use[1], with over 50 years of safety and efficacy data since it was approved in injectable form in 1971[2]. NARCAN® Nasal Spray has been at the forefront of many important developments and milestones in the fight to reduce opioid overdose deaths, including:

- **November 2015 FDA Approval:** The U.S. approval of prescription NARCAN® Nasal Spray revolutionized overdose intervention, introducing a user-friendly, non-injectable form of naloxone. Upon the launch in early 2016, individuals on the frontlines of the opioid crisis were early adopters using the life-saving medication in the event of an opioid overdose emergency.
- **February 2016 Prescription Launch:** Since the launch of NARCAN® Nasal Spray in 2016, over 85 million doses have been distributed across North America, saving countless lives and fundamentally transforming opioid overdose preparedness.
- **Supported by First Responders:** Police, firefighters and emergency medical technicians (EMTs) integrated NARCAN® Nasal Spray into their emergency protocols, equipping first responders with an effective tool to quickly reverse opioid overdoses and help save lives.
- **Widespread Distribution by Harm Reduction Organizations:** With support from state and local programming, harm reduction organizations can distribute NARCAN® Nasal Spray to at-risk populations, putting naloxone into the hands of those who need it most.
- **Introduction of Good Samaritan Laws:** Important legislative measures were taken in 48 states and in Washington, D.C. to enact Good Samaritan Laws, which created legal protections for people who administer naloxone, and/or call for help in the event of an overdose.
- **2018 Acquisition of NARCAN® Nasal Spray and Launch of NARCANDirect®**: In 2018, Emergent acquired Adapt Pharma and its flagship product, NARCAN® Nasal Spray. The same year, NARCANDirect® was launched to provide streamlined access to opioid overdose reversal products for emergency medical services, law enforcement, fire departments, government agencies, educational institutions and community-based naloxone distribution programs.
- **2023 OTC FDA Approval and Retail Launch:** Following U.S. FDA approval in March 2023, NARCAN® Nasal Spray became the first OTC naloxone treatment available nationwide in pharmacies, grocery stores and online in September, breaking down barriers to access and normalizing buying and carrying naloxone for consumers.
- **Rallying Americans Nationwide to Be Ready to Rescue:** On the heels of OTC approval, the launch of the *Ready to Rescue* campaign targeted a key audience with college campus activations, as rates of opioid misuse are highest amongst people ages 18-25.[3] The initiative has raised awareness of opioid risks and helped break down the stigma associated with opioid poisoning emergencies.
- **Expanded Range of Products to Support Customer Needs**: To better support customers, Emergent now offers NARCAN® Nasal Spray Wall Unit Kits, which include a wall unit cabinet with alarm, poster and wayfinder sign, as well as convenience kits, which include medical grade components including one hard case with internal pockets, a CPR mask and a pair of nitrile examination gloves.

The Centers for Disease Control and Prevention reported a nearly 32 percent decrease in opioid overdose deaths in 2024.[4] Increased access to naloxone products like OTC NARCAN® Nasal Spray is one of several factors that have contributed to this decline. Despite progress, opioid overdose deaths remain the leading cause of accidental death in the U.S and illicitly manufactured fentanyl and new analogues such as nitazenes and kratom are appearing in non-opioid drugs and leading to fatalities.[5,6]

Recently, the American Heart Association issued new guidelines with updated recommendations for treating people experiencing a suspected opioid overdose. For the first time, the guidelines provide public access instructions on when to use naloxone and recommend policies to facilitate public

access to naloxone alongside AEDs or defibrillator devices due to its potential to save lives.[6] In an effort to further scientific leadership around naloxone, Emergent has launched Project NEXUS, a strategic initiative to generate real-world evidence across naloxone dosages and expand access to life-saving treatment.

"Since the approval of NARCAN® Nasal Spray in 2015, Emergent has strived to ensure availability to those most at risk who are in need of naloxone, engaging with pharmacists, community-based organizations, harm reduction, law enforcement, departments of health and other key stakeholders," said Paul Williams, senior vice president, head of products business, global government & public affairs at Emergent. "While we celebrate the progress that has been made in the last 10 years, we know our work is not done. As the opioid crisis continues to evolve and take far too many lives, Emergent reaffirms our commitment to ensuring that life-saving tools are readily available as we aim to help create a safer future."

As the leading U.S. supplier of nasal naloxone, Emergent remains focused on saving as many lives as possible through increased access, awareness, and availability of NARCAN® Nasal Spray 4 mg and KLOXXADO® (naloxone HCl) Nasal Spray 8 mg. In honor of Emergent's long-standing commitment to saving lives, the Victoria's Voice Foundation awarded the company with its 2025 Corporate Hero Award that recognizes companies who have made significant contributions in the fight against the opioid epidemic through awareness, education, access and policy efforts.

To learn more about how you can join the fight against opioid overdose deaths and be ready to rescue in an opioid emergency, please visit NARCAN.com.

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.

Important Safety Information for KLOXXADO® (naloxone HCl) Nasal Spray 8 mg

What is KLOXXADO® Nasal Spray?

- KLOXXADO® Nasal Spray is a prescription medicine used for the treatment of an opioid emergency such as an overdose or a possible opioid overdose in adults and children with signs of breathing problems and severe sleepiness or not being able to respond.
- KLOXXADO® Nasal Spray is to be given right away and does not take the place of emergency medical care.
- Get emergency medical help right away after giving the first dose of KLOXXADO® Nasal Spray, even if the person wakes up.

What is the most important information I should know about KLOXXADO® Nasal Spray?

Get emergency medical help right away after giving the first dose of KLOXXADO® Nasal Spray. The signs and symptoms of an opioid emergency can return after KLOXXADO® Nasal Spray is given. If this happens, give another dose after 2 to 3 minutes using a new KLOXXADO® Nasal Spray and watch the person closely until emergency help is received.

The medicine in KLOXXADO® Nasal Spray is safe to use in people who are not taking opioids. KLOXXADO® Nasal Spray is not intended for self-administration.

What should I tell my healthcare provider (pharmacist or prescriber) before using KLOXXADO® Nasal Spray?

Before using KLOXXADO® Nasal Spray, tell your healthcare provider about all of your medical conditions, including if you:

- have heart problems
- are pregnant or plan to become pregnant. Use of KLOXXADO® Nasal Spray may cause withdrawal symptoms in your unborn baby. Your unborn baby should be examined by a healthcare provider right away after you use KLOXXADO® Nasal Spray.
- are breastfeeding or plan to breastfeed. It is not known if KLOXXADO® Nasal Spray passes into your breast milk.

What are the possible serious side effects of KLOXXADO® Nasal Spray?

KLOXXADO® Nasal Spray may cause sudden opioid withdrawal symptoms including body aches, diarrhea, increased heart rate, fever, runny nose, sneezing, goose bumps, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, stomach cramping, 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.

Who should not use KLOXXADO® Nasal Spray?

Do not use KLOXXADO® Nasal Spray if you are allergic to naloxone hydrochloride or any of the ingredients in KLOXXADO® Nasal Spray.

What are the most common side effects of KLOXXADO® nasal spray?

The most common side effects of KLOXXADO® Nasal Spray in adults include stomach-area (abdomen) pain, weakness, dizziness, headache, nose (nasal) discomfort, and a feeling like you are going to faint.

These are not all of the possible side effects of KLOXXADO® Nasal Spray. Please see **full Prescribing Information**, including Patient Information, which includes a more complete discussion of the risks associated with KLOXXADO® Nasal Spray. Always contact your healthcare provider

(pharmacist or prescriber) if you have questions or experience any side effects.

You are encouraged to report negative side effects to the FDA at: 1-800-FDA-1088 or www.fda.gov/medwatch. You can also contact Hikma Specialty USA Inc. at: us.hikma@primevigilance.com or call 1-877-845-0689 or 1-800-962-8364.

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About Emergent BioSolutions
At Emergent, our mission is to protect and save lives. For over 25 years, we've been at work preparing those entrusted with protecting public health. We deliver protective and life-saving solutions for health threats like smallpox, mpox, botulism, Ebola, anthrax and opioid overdose emergencies. To learn more about how we help prepare communities around the world for today's health challenges and tomorrow's threats, visit our website and follow us on LinkedIn, X, Instagram, Apple Podcasts and Spotify.

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[1]Wermeling, D.P., (2015). Review of naloxone safety for opioid overdose: practical considerations for new technology and expanded public access. *Therapeutic Advances in Drug Safety*, 6(1), pp.20-31. doi: 10.1177/2042098614564776.

[2]Massachusetts Department of Public Health. Naloxone facts and formulations. Available at: https://www.mass.gov/info-details/naloxone-facts-and-formulations/. Accessed: November 5, 2025.

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[4] NCHS, National Vital Statistics System. Estimates for 2024 and 2025 are based on provisional data. Estimates for 2015-2023 are based on final data (available from: https://www.cdc.gov/nchs/nvss/mortality_public_use_data.htm).

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[6]Gershman, K., Timm, K., Frank, M., Lampi, L., Melamed, J., Gerona, R. & Monte, A.A. (2019) 'Deaths in Colorado attributed to kratom', *The New England Journal of Medicine*, 380(1), pp. 97-98. doi: 10.1056/NEJMc1811055.

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