Emergent BioSolutions Reports FDA Advisory Committees' Unanimous Vote in Favor of NARCAN® (naloxone HCl) Nasal Spray for Over-the-Counter Use

February 15, 2023

- If approved by the FDA, NARCAN Nasal Spray will be the first 4 mg naloxone nasal spray switched from prescription status to over-the-counter use

GAITHERSBURG, Md., Feb. 15, 2023 (GLOBE NEWSWIRE) -- Today, Emergent BioSolutions Inc. (NYSE:EBS) announced the U.S. Food and Drug Administration (FDA) Nonprescription Drugs Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee have unanimously voted in favor (a total of 19 votes) that the benefit-risk profile of NARCAN® (naloxone HCl) Nasal Spray is supportive of its use as a nonprescription opioid overdose reversal agent. Emergent presented an overview of its over-the-counter (OTC) development program, the medical need, Human Factors study data and seven years of post-marketing safety data. The FDA is not bound by the committees' guidance but will take its advice into consideration.

"This favorable recommendation marks another important step forward to broaden access to NARCAN Nasal Spray for those who may be at risk of an opioid overdose," said Paul Williams, SVP and Products Business Head, Emergent BioSolutions. "Today's vote reaffirms our confidence in the safe and effective use of NARCAN in the community setting. We want to thank the participants in the open public hearing who shared their insights and personal experiences informing the need to make NARCAN more readily available over the counter."

According to the United States Centers for Disease Control and Prevention, more than 107,000 Americans lost their lives to a drug overdose in 2021, of which more than 70,000 were a result of using synthetic opioids containing fentanyl.[1] The rise in opioid-related deaths, including the increase associated with use of fentanyl, specifically during the COVID-19 pandemic, has prioritized the need to expand access to opioid overdose reversal treatment.

"Bystanders are present at nearly half of fatal overdoses, yet naloxone is administered in only a small percentage of those cases," [2] said Dr. Joshua Lynch, Clinical Associate Professor of Emergency and Addiction Medicine, University at Buffalo Jacobs School of Medicine and Biomedical Sciences. "The reality is accidental overdoses can happen to anyone, anywhere, at any time, and we can all do our part by being prepared to help like we would in any other emergency. With access to over-the-counter naloxone, we would have a critical opportunity to close this gap and reduce the number of opioid-related deaths."

Emergent was the first company to submit a supplemental New Drug Application for OTC and received Priority Review by the FDA. If approved, NARCAN would be the first 4 mg naloxone nasal spray available OTC in the U.S. The Prescription Drug User Fee Act goal date is March 29, 2023. Emergent will continue to work with policymakers, retailers, advocates and other stakeholders to help ensure policies and solutions are implemented to increase access and awareness of this potentially lifesaving medicine.

INDICATION AND IMPORTANT SAFETY INFORMATION

What is NARCAN Nasal Spray?

- NARCAN Nasal Spray is a prescription medicine used for the emergency treatment of a known or suspected opioid overdose emergency with signs of breathing problems and severe sleepiness or not being able to respond.
- NARCAN 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 NARCAN Nasal Spray, even if the person wakes up.

NARCAN Nasal Spray is safe and effective in children for known or suspected opioid overdose.

Who should not use NARCAN Nasal Spray?

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

What is the most important information I should know about NARCAN Nasal Spray? NARCAN Nasal Spray is used to temporarily reverse the effects of opioid medicines. The medicine in NARCAN Nasal Spray has no effect in people who are not taking opioid medicines. Always carry NARCAN Nasal Spray with you in case of an opioid overdose.

1. Use NARCAN Nasal Spray right away if you or your caregiver think signs or symptoms of an opioid overdose are present, even if you are not sure, because an opioid overdose can cause severe injury or death. Signs and symptoms of an opioid overdose may include:
    - unusual sleepiness and 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

2. Family members, caregivers, or other people who may have to use NARCAN Nasal Spray in an opioid overdose should know where NARCAN Nasal Spray is stored and how to give NARCAN Nasal Spray before an opioid overdose happens.
3. **Get emergency medical help right away after giving the first dose of NARCAN Nasal Spray.** Rescue breathing or CPR (cardiopulmonary resuscitation) may be given while waiting for emergency medical help.
4. The signs and symptoms of an opioid overdose can return after NARCAN Nasal Spray is given. If this happens, give another dose after 2 to 3 minutes using a new NARCAN Nasal Spray device and watch the person closely until emergency help is received.

What should I tell my healthcare provider before using NARCAN Nasal Spray?

Before using NARCAN 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 NARCAN 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 NARCAN Nasal Spray.
- are breastfeeding or plan to breastfeed. It is not known if NARCAN Nasal Spray passes into your breast milk.

Tell your healthcare provider about the medicines you take, including prescription and over-the-counter medicines, drugs, vitamins, and herbal supplements.

What are the possible side effects of NARCAN Nasal Spray?

NARCAN Nasal Spray may cause serious side effects, including:

Sudden opioid withdrawal symptoms which can be severe. In someone who has been using opioids regularly, opioid withdrawal symptoms can happen suddenly after receiving NARCAN Nasal Spray and may include:

- 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
- increased blood pressure

Some patients may show aggressive behavior upon abrupt reversal of an opioid overdose.

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.

These are not all of the possible side effects of NARCAN Nasal Spray. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 or http://www.fda.gov/medwatch.

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Please see full Prescribing Information.

For additional information on NARCAN® Nasal Spray, please visit www.NARCAN.com.

About Emergent BioSolutions
At Emergent, our mission is to protect and enhance life. For over 20 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, Twitter, and Instagram.

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, including statements regarding the development of Over-the-Counter NARCAN® (naloxone HCl) Nasal Spray, are forward-looking statements. We generally identify forward-looking statements by using words like "anticipate," "believe," "continue," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "should," "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. We cannot guarantee that any forward-looking statement will be accurate. Readers should realize that if underlying assumptions prove inaccurate 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 statement. Any forward-looking statement speaks only as of the date of this press release, and, except as required by law, we do not undertake 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 identified in our periodic reports filed with the Securities and Exchange Commission, when evaluating our forward-looking statements.

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[1] Centers for Disease Control and Prevention. (2022, May 11). U.S. overdose deaths in 2021 increased half as much as in 2020 - but are still up 15%. Centers for Disease Control and Prevention. Retrieved November 21, 2022, from https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2022/202205.htm

[2] Mattson CL, et al. Opportunities to Prevent Overdose Deaths Involving Prescription and Illicit Opioids, 11 States, July 2016-June 2017. *MMWR Morb Mortal Wkly Rep*. 2018;67(34):945-951. Published 2018 Aug 31. doi:10.15585/mmwr.mm6734a2

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