U.S. FDA Approves Over-the-Counter Designation for Emergent BioSolutions' NARCAN® Nasal Spray, a Historic Milestone for the Opioid Overdose Emergency Treatment

March 29, 2023

- NARCAN® Naloxone HCl Nasal Spray 4 mg is currently the first and only prescription strength naloxone nasal spray to receive over-the-counter status in the U.S., which is a critical step toward broadening access
- Expected over-the-counter availability is anticipated by late summer of this year

GAITHERSBURG, Md., March 29, 2023 (GLOBE NEWSWIRE) -- Today, Emergent BioSolutions Inc. (NYSE: EBS) announced that the U.S. Food and Drug Administration (FDA) has approved NARCAN® Naloxone HCl Nasal Spray 4 mg as an over-the-counter (OTC) emergency treatment of opioid overdose. This decision comes at a time when approximately every eight minutes, a person dies from an opioid overdose and research shows the epidemic is escalating in the U.S. with the rise in synthetic opioids. By offering NARCAN® Nasal Spray as an OTC treatment, anyone will be able to access it without a prescription, which is an important step in the fight to reduce the number of opioid overdose deaths occurring each day.

"Our lives changed forever when our 16-year-old son, Sammy, passed away in his bedroom after taking a medication laced with fentanyl that he purchased through a social media site," said Dr. Laura Berman, psychotherapist, PhD and well-known author, radio, TV, and podcast host. "Since Sammy's passing, we've learned that if we had a form of naloxone in our home, we may have been able to save him. With today's over-the-counter approval of NARCAN® Nasal Spray, more families can be prepared, so they don't experience the same heartache."

NARCAN® Nasal Spray was developed for use in the community setting and more than 44 million doses have been distributed since its launch in 2016. This prescription-to-OTC approval is supported by Human Factors study data, an updated Drug Facts label, pharmacovigilance data collected from various public sources, and seven years of post-marketing safety data. The new OTC product will have the same formulation, device design, and original prescription strength (4 mg), which are important features and benefits to help counteract the effects of opioids, including fentanyl, in the community setting.

"Today's landmark FDA OTC approval for NARCAN ® Nasal Spray marks a historic milestone as we have delivered on our commitment to make this important emergency treatment widely accessible, given the alarming rates of opioid overdoses occurring across the country," said Robert G. Kramer, president and CEO of Emergent BioSolutions. "We are dedicated to improving public health and assisting those working hard to end the opioid crisis – so now with leaders across government, retail and advocacy groups, we must work together to continue increasing access and availability, as well as educate the public on the risks of opioid overdoses and the value of being prepared with NARCAN® Nasal Spray to help save a life."

Emergent anticipates NARCAN® Nasal Spray will be available on U.S. shelves and at online retailers by the late summer to account for manufacturing changes that will be implemented to support nonprescription packaging, as well as supply chain modifications. In the meantime, the prescription product will remain in readily available supply through current access channels, including pharmacies through standing order or co-prescription laws and through community distribution. For more information, 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.

About Emergent BioSolutions

At Emergent, our mission is to protect and enhance life. For 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, 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 and commercial availability 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 U.S. Securities and Exchange Commission, when evaluating our forward-looking statements.

Emergent BioSolutions Contacts:

Media:
Matt Hartwig

Senior Director, Media Relations
240-760-0551
mediarelations@ebsi.com

Investors:
Robert G. Burrows
Vice President, Investor Relations
240-631-3280
burrowsr@ebsi.com

A PDF accompanying this announcement is available at http://ml.globenewswire.com/Resource/Download/23d7ac89-2488-459b-b34e-1ec7a971ecb8

Source: Emergent BioSolutions