

COVID-19 Vaccine Drug Substance Manufactured by Emergent BioSolutions Authorized as Part of Johnson & Johnson's Emergency Use Authorization

June 11, 2021

 Emergent continues to work with the FDA to address identified observations at Bayview facility in order to release additional batches and resume production

GAITHERSBURG, Md., June 11, 2021 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE:EBS) today announced that two batches of COVID-19 vaccine manufactured by Emergent BioSolutions at its Baltimore Bayview facility were determined to be suitable for use by the U.S. Food & Drug Administration (FDA) and have been authorized as part of Johnson & Johnson's Emergency Use Authorization (EUA).

"We are pleased that these initial doses of the Johnson & Johnson COVID-19 vaccine will be available to protect millions of people from this deadly disease," said Robert G. Kramer, president and chief executive officer of Emergent. "We look forward to working with the FDA and Johnson & Johnson toward the release of additional batches and resuming production at our Bayview facility."

Emergent is actively addressing issues identified by the FDA at its Bayview facility and plans to resume manufacturing of the Johnson & Johnson COVID-19 vaccine drug substance after Emergent, Johnson & Johnson, and FDA are confident that the steps taken have remedied shortcomings.

For nearly a decade, Emergent has been working closely with the U.S. government to ensure that manufacturing capacity stands at the ready to address public health emergencies. This foresight of the U.S. government led to the designation of Emergent's Baltimore Bayview facility as a Center for Innovation in Advanced Development and Manufacturing (CIADM) in 2012. This agreement was first established as a public-private partnership for influenza pandemic preparedness. Since mid-2020, Emergent has harnessed its capabilities to rapidly build and scale up capacity to manufacture bulk drug substance for Johnson & Johnson's COVID-19 vaccine.

About Emergent BioSolutions

Emergent BioSolutions is a global life sciences company whose mission is to protect and enhance life. Through Emergent's specialty products and contract development and manufacturing services, Emergent is dedicated to providing solutions that address public health threats. Through social responsibility, Emergent aims to build healthier and safer communities. Emergent aspires to deliver peace of mind to its patients and customers so they can focus on what's most important in their lives. In working together, Emergent envisions protecting or enhancing 1 billion lives by 2030. For additional information, visit Emergent's website and follow Emergent 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. Any statements, other than statements of historical fact, including statements regarding manufacturing capacity and supply and vaccination goals and any other statements containing the words "believes," "expects," "anticipates," "intends," "plans," "estimates," and similar expressions, are forward-looking statements. These 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. Investors should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. Investors 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 such forward-looking statements, including our ability to produce vaccine bulk drug substance on a timely basis and in sufficient quantities to meet demand. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. Investors should consider this cautionary statement, as well as the risk factors identified in our periodic reports filed with the SEC, when evaluating our forward-looking statements.

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Source: Emergent BioSolutions