



Emergent BioSolutions Announces FDA Approval of Change in Storage Conditions and Transfer of Manufacturing for Its Cholera Vaccine

June 4, 2019

GAITHERSBURG, Md., June 04, 2019 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE:EBS) today announced approval by the U.S. Food and Drug Administration (FDA) of the Prior Approval Supplement (PAS) submitted by the company for its oral cholera vaccine, Vaxchora[®] (Cholera Vaccine, Live, Oral). The PAS supports the change in storage conditions of the vaccine from frozen to refrigerated at 2-8°C and the transfer of bulk drug substance manufacturing from Emergent's product development facility in San Diego to its manufacturing facility in Bern, Switzerland. The PAS also covers changes in labeling regarding these developments. The company's oral cholera vaccine is the only FDA-licensed vaccine for the prevention of cholera caused by *Vibrio cholerae* serogroup O1, a potentially serious intestinal disease.

"Emergent is pleased with this FDA approval that enables a more robust supply chain process for our oral cholera vaccine and maximizes capacity utilization of our manufacturing facilities," said Sean Kirk, executive vice president, manufacturing and technical operations at Emergent BioSolutions. "This development positions the company to expand into new markets as we prepare for European launch in 2020."

In the U.S., the vaccine is marketed as Vaxchora[®]. The vaccine is indicated for active immunization against disease caused by *Vibrio cholerae* serogroup O1. Vaxchora[®] is approved for use in adults 18 through 64 years of age traveling to cholera-affected areas. Limitations of Use: The effectiveness of Vaxchora[®] has not been established in persons living in cholera-affected areas. The effectiveness of Vaxchora[®] has not been established in persons who have pre-existing immunity due to previous exposure to *V. cholerae* or receipt of a cholera vaccine. Vaxchora[®] has not been shown to protect against disease caused by *V. cholerae* serogroup O139 or other non-O1 serogroups. It was approved by the FDA in June 2016 as the only vaccine available in the U.S. for active immunization against cholera.

For full Prescribing Information, please visit www.vaxchora.com.

About Cholera

Cholera, transmitted by ingestion of food and water contaminated with *Vibrio cholerae*, may present with a broad range of symptoms. Cholera commonly presents as watery diarrhea, but may also be asymptomatic or, in severe cases, characterized by profuse watery diarrhea.ⁱ If untreated, these severe cases may lead to dehydration, hypovolemic shock and death within hours.ⁱ With limited surveillance capacities, as well as social, economic and political disincentives, cholera is an underreported disease. The World Health Organization (WHO) estimates that only 5-10% of cases occurring annually are officially reported.^{ii,iii} Non-vaccine interventions to prevent cholera infection include the avoidance of contaminated water and food and frequent handwashing.ⁱ In May 2017, the CDC published its recommendation for the use of Vaxchora in adults 18-64 years traveling from the U.S. to areas of active cholera transmission.^{iv}

About Emergent BioSolutions

Emergent BioSolutions Inc. is a global life sciences company seeking to protect and enhance life by focusing on providing specialty products for civilian and military populations that address accidental, deliberate, and naturally occurring public health threats. We aspire to be a Fortune 500 company recognized for protecting and enhancing life, driving innovation, and living our values. Additional information about the company may be found at www.emergentbiosolutions.com. Find us on LinkedIn and follow us on Twitter @emergentbiosolu and Instagram @life_at_emergent.

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 related to our ability to respond to increased global product demand, maximizing the capacity utilization of our facilities and expansion of our supply chain, customer base and market area, 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 obtain and maintain regulatory approvals; and our commercialization, marketing and manufacturing capabilities. 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.

ⁱ Wong KK, Burdette E, and Mintz ED. Cholera. Centers for Disease Control and Prevention website. <https://wwwnc.cdc.gov/travel/yellowbook/2018/infectious-diseases-related-to-travel/cholera>. Updated May 31, 2017. Accessed May 2019.

ⁱⁱ Ali M *et al.* Updated Global Burden of Cholera in Endemic Countries. 2015; PLoS Negl Trop Dis. 2015 Jun 4;9(6):e0003832. doi: 10.1371/journal.pntd.0003832. eCollection 2015.

ⁱⁱⁱ WHO (2016) Cholera surveillance and number of cases. Geneva: World Health Organization. https://www.who.int/gho/epidemic_diseases/cholera/cases_text/en/. Accessed May 2019.

^{iv} Wong KK et al. *Recommendations of the advisory committee on immunization practices for use of cholera vaccine. MMWR. 2017; 66 (18): 482-485.*

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