

EMERGENT

Emergent BioSolutions Receives Health Canada Approval of BioThrax® (Anthrax Vaccine Adsorbed)

December 17, 2018

GAITHERSBURG, Md., Dec. 17, 2018 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE:EBS) today announced that Health Canada has approved the company's New Drug Submission (NDS) for its anthrax vaccine, BioThrax® (Anthrax Vaccine Adsorbed). BioThrax is indicated for active immunization for the prevention of disease caused by *Bacillus anthracis*, in individuals 18 through 65 years of age, whose occupation or other activities place them at risk of exposure, regardless of the route of exposure. BioThrax is administered in a three-dose primary schedule (0, 1 and 6 months) with boosters at three-year intervals recommended thereafter. BioThrax was approved under the Extraordinary Use New Drug Regulations, which provide a regulatory pathway for products for which collecting clinical information for its intended use in humans is logistically or ethically not possible.

"With the growing awareness of biological and chemical threats around the globe, Emergent is committed to partnering with allied governments and providing preparedness solutions to meet their national security needs," said Abbey Jenkins, senior vice president and vaccines and anti-infectives business unit head, at Emergent BioSolutions. "We are pleased to receive Health Canada licensure of BioThrax, fulfilling our commitment to the Canadian government, and enabling future procurement of this critical medical countermeasure. We look forward to continuing our decades-long partnership in our quest to fulfill our mission – to protect and enhance life."

BioThrax is designated by Health Canada as an innovative drug giving it market exclusivity for eight years. Earlier this year, Emergent completed the Mutual Recognition Procedure for BioThrax expanding licensure of BioThrax in five European countries, namely, the U.K., Poland, France (marketed as BaciThrax), Italy, and the Netherlands, in addition to Germany, where BioThrax received market authorization in 2013.

About BioThrax

BioThrax is also licensed by the U.S. Food and Drug Administration for the active immunization for the prevention of disease caused by *Bacillus anthracis* in persons 18 through 65 years of age for both pre-exposure and post-exposure prophylactic use. Please follow links for full [U.S. prescribing information](#) and for full Canadian prescribing information in [English](#) or in [French](#).

BioThrax has also received market authorization from the Health Sciences Authority in Singapore and the Paul-Ehrlich Institut in Germany.

Where approved in Europe, BioThrax is indicated for prevention of disease caused by *Bacillus anthracis* in adults at risk of exposure. BioThrax should be used in accordance with official recommendations, where available. BioThrax is administered in a three-dose primary schedule (0, 1 and 6 months) with boosters at three-year intervals recommended thereafter. Please follow link for full details of [EU prescribing information](#).

The safety and efficacy of BioThrax have not been established in pediatric or geriatric populations. Individuals are not considered protected until they have completed the three-dose primary immunization series. Vaccination with BioThrax may not protect all individuals.

BioThrax is manufactured from a culture filtrate, made from a non-virulent strain of *Bacillus anthracis*. Over 14 million doses of BioThrax have been administered to more than three million individuals.

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, intentional, 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.

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