Emergent BioSolutions Receives EMA Prime Designation for Its Chikungunya Virus VLP Vaccine Candidate

October 10, 2019

GAITHERSBURG, Md., Oct. 10, 2019 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE:EBS) today announced that the company's chikungunya virus (CHIKV) virus-like particle (VLP) vaccine candidate, CHIKV VLP, was granted PRIority MEdicines, or PRIME, designation by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) during its September meeting. The PRIME scheme is designed to enhance support for the development of medicines that target an unmet medical need and that may offer a major therapeutic advantage over existing treatments, or benefit patients without preventative or treatment options. The CHIKV VLP vaccine candidate is being developed for the prevention of disease caused by chikungunya virus infection, an illness that spreads through mosquito bites and for which no vaccine or treatment is available.

Abbey Jenkins, senior vice president and vaccines business unit head, stated, "Emergent is pleased to receive this important EMA designation and encouraged by the strength of our early data package, including results from the interim analysis of our Phase 2 safety and immunogenicity study for our CHIKV VLP vaccine candidate announced last April. We are highly motivated to help address the significant unmet need presented by the chikungunya virus, considered a global threat due to the debilitating nature of the resulting illness and potential magnitude of its ability to spread.[1] We look forward to working with the EMA to execute on our development plan, which contemplates initiation of a pivotal trial in 2020."

Under the PRIME scheme, which supports promising medicines for unmet medical needs based on early clinical data, eligible companies can benefit from enhanced interaction and early dialogue with the EMA to help optimize development plans and expedite evaluation such that medicines under development can reach patients faster.

The CHIKV VLP vaccine candidate is licensed from the National Institute of Allergy and Infectious Diseases at the National Institutes of Health. It received Fast Track designation from the U.S. Food and Drug Administration in May 2018.

About the Chikungunya virus
Chikungunya virus is spread to people through infected mosquitoes. Symptoms include fever, joint pain, headache, muscle pain, joint swelling, or rash. Chikungunya outbreaks have occurred in countries in Africa, Asia, Europe, and the Indian and Pacific Oceans. The chikungunya virus was found for the first time in the Americas on islands in the Caribbean in 2013. According to the Centers for Disease Control and Prevention, there is a risk that the virus will be imported to new areas by infected travelers. Currently, there is no vaccine to prevent or medicine to treat chikungunya virus infection.

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 regarding the effectiveness of the product candidate, executing on our development plan and the initiation of a pivotal trial next year, 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 the success of the planned development program; the timing of and ability to obtain and maintain regulatory approvals for the product candidate; 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.

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[1] Braira Wahida, Amjad Alia, Shazia Rafiquea, Muhammad Idreesa. Global expansion of chikungunya virus: mapping the 64-year history. International Journal of Infectious Diseases 2017; 58: 69–76

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