Emergent BioSolutions Announces Interim Results From Phase 2 Study Evaluating CHIKV-VLP, Chikungunya Virus Vaccine Candidate

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GAITHERSBURG, Md., April 16, 2019 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE:EBS) today announced results from the interim analysis of its Phase 2 clinical study evaluating the safety and immunogenicity of the company's chikungunya virus virus-like particle (CHIKV-VLP) vaccine candidate across a series of dosing regimens. The interim analysis has shown that with a single dose administered, up to 98% of study participants produced a neutralizing antibody response against the chikungunya virus (CHIKV) by Day 7. Further, the immune response was shown to be persistent through the six-month visit, including in the one-dose regimen.

"Emergent is highly encouraged about our vaccine candidate as the interim data suggest that a single dose of the vaccine was able to generate a positive immune response, which persisted through the study participants' visits at six months," said Abbey Jenkins, senior vice president and vaccines and anti-infectives business unit head. "Chikungunya virus infection represents a significant unmet medical need – having no vaccine or treatment available – despite its emergence as a global threat because of the highly debilitating nature of the associated disease and unprecedented magnitude of its spread.[1] We look forward to completing the data set analysis and finalizing our development plan, which could allow for initiation of a pivotal trial next year."

Virus-like particle (VLP) vaccines are multi-protein structures that mimic the organization and conformation of naturally occurring viruses, without the viral genome, that could potentially promote a stronger immune response and increased antibody production. Studies have shown that VLP vaccines are highly immunogenic, have a proven safety record, and typically elicit high titer neutralizing antibodies needed to protect against chikungunya virus.[2]

This Phase 2 parallel-group, randomized, double-blind, dose-finding study involved 415 healthy adults in three U.S. sites. Participants were given a 1- or 2-dose series with or without an adjuvant over a 4-week period. Seroconversion occurred in 74% to 98% of subjects within 7 days after one dose, and in all subjects by 28 days after the last dose. The vaccine candidate was well-tolerated across all study arms and no significant vaccine-related safety concerns have been identified in analyses to date.

The CHIKV-VLP chikungunya virus 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, 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.

[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

[2] Akahata W, Yang ZY, Andersen H, et al. A virus-like particle vaccine for epidemic chikungunya virus protects nonhuman primates against infection.

Nat Med 2010; 16: 334–38.

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