Emergent BioSolutions Receives Department of Defense Award to Evaluate Chikungunya Vaccine Candidate in Post-Approval Field Efficacy Study Using Model-Guided Approach

November 14, 2022

Emergent partners with the Armed Forces Research Institute of Medical Sciences for its capabilities in Chikungunya virus surveillance and field studies

GAITHERSBURG, Md., Nov. 14, 2022 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE:EBS) announced today a research award by the U.S. Department of Defense (DoD) Congressionally Directed Medical Research Programs (CDMRP) to evaluate efficacy of the company's single-dose chikungunya virus virus-like particle (CHIKV VLP) vaccine candidate. Emergent will begin the planning phase, the first of two phases, in collaboration with the Armed Forces Research Institute of Medical Sciences (AFRIMS) and academic partners, to enable a post-approval field efficacy study in areas with active chikungunya virus (CHIKV) transmission.

"Emergent is pleased to gain the support of the CDMRP to verify the clinical benefit of our CHIKV VLP vaccine candidate for CHIKV disease through a post-approval field efficacy study," said Chris Cabell, M.D., chief medical officer and SVP clinical development at Emergent BioSolutions. "We look forward to combining our product development expertise with the capabilities of AFRIMS in chikungunya epidemiology and field studies, and of our academic partners in infectious disease modeling and efficacy trial design, to find ways to address chikungunya disease, a public health threat for which no vaccine or treatment exists."

AFRIMS is a research directorate in Thailand and a component of the Walter Reed Army Institute of Research (WRAIR) in Maryland, USA. An important element of the AFRIMS mission is to support the development of vaccines against viruses that are endemic in the Southeast Asia region.

The planned post-approval study, a multicenter Phase 3b clinical study, will evaluate the vaccine candidate's efficacy in preventing CHIKV disease and assess the utility of a model-guided disease surveillance framework to optimize execution of a field efficacy trial using CHIKV as a model emerging pathogen.

This work was supported by the Office of the Assistant Secretary of Defense for Health Affairs and the Defense Health Agency J9, Research and Development Directorate, or the U.S. Army Medical Research Acquisition Activity at the U.S. Army Medical Research and Development Command through the Peer Reviewed Medical Research Program (PRMRP) under Award No. W81XWH2210481, with a total program budget of approximately $10 million for both the planning and clinical study phases.

The PRMRP supports research across the full range of science and medicine, with an underlying goal of enhancing the health, care, and well-being of military service members, veterans, retirees, and their family members. Opinions, interpretations, conclusions, and recommendations are those of the author and are not necessarily endorsed by the Department of Defense.

About the chikungunya virus
Chikungunya virus is spread to people by infected mosquitoes. Symptoms include fever, incapacitating joint pain, headache, muscle pain, joint swelling or rash. The geographic distribution of CHIKV has expanded to more than 100 countries and territories worldwide.

About the CHIKV VLP vaccine candidate
Emergent BioSolutions' CHIKV VLP chikungunya virus vaccine candidate is a single dose VLP-based vaccine in clinical development for active immunization against chikungunya disease. It is currently being investigated in two pivotal phase 3 trials. The CHIKV VLP candidate is licensed from the National Institute of Allergy and Infectious Diseases at the National Institutes of Health. It received Breakthrough Therapy designation and Fast Track designation from the U.S. Food and Drug Administration in October 2020 and May 2018, respectively, and PRIME (PRIority MEdicines) designation from the European Medicines Agency in September 2019.

About Emergent BioSolutions
At Emergent, our mission is to protect and enhance life. For over 20 years, we've been at work defending people from things we hope will never happen—so we are prepared, just in case they ever do. We provide solutions for complex and urgent public health threats through a portfolio of vaccines and therapeutics that we develop and manufacture for governments and consumers. We also offer a range of integrated contract development and manufacturing services for pharmaceutical and biotechnology customers. To learn more about how we plan to protect or enhance 1 billion lives by 2030, visit our website and follow us 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 our ability to fill the need for an approved vaccine to prevent chikungunya disease, the effectiveness of the product candidate, and executing on our development program, 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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Source: Emergent BioSolutions