Emergent BioSolutions Announces Initiation of Pivotal Phase 3 Study Evaluating the Safety and Immunogenicity of Its Single-Dose Chikungunya Vaccine Candidate, CHIKV VLP

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GAITHERSBURG, Md., Oct. 15, 2021 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE:EBS) today announced the first participant dosed in its pivotal phase 3 study evaluating the safety and immunogenicity of the company's investigational chikungunya virus (CHIKV) virus-like particle (VLP) vaccine candidate, CHIKV VLP, in a single dose. CHIKV VLP is the only VLP-based vaccine currently in clinical development for active immunization against chikungunya disease.

"Emergent has achieved a major milestone as we begin our phase 3 study for our single-dose chikungunya vaccine candidate," said Karen L. Smith, M.D., Ph.D., executive vice president and chief medical officer at Emergent BioSolutions. "I am proud of the Emergent team for bringing us a step closer to potentially having a critical solution to address this important disease for which no vaccine or treatment is currently available. A true demonstration of our commitment to our mission – to protect and enhance life."

The goal of this multi-center, randomized, double blind, placebo-controlled study is to evaluate the safety and immunogenicity of the CHIKV VLP vaccine candidate in healthy individuals aged 12 to 64 as well as to demonstrate the consistency of the chikungunya virus (CHIKV) serum neutralizing antibody (SNA) response across three manufactured vaccine candidate lots. The study will observe the CHIKV SNA response at day 22 as measured by geometric mean titer and seroresponse rate and will enroll at least 3,150 participants in up to 49 U.S. sites.

The structure of the CHIKV VLP is nearly identical to the wild-type virus but does not pose a risk of replication. Studies have shown that in general, other VLP vaccines are highly immunogenic, safe, and typically elicit high titer neutralizing antibodies, which are needed to protect against chikungunya virus.[i,ii] There is currently no licensed vaccine, VLP or otherwise, to prevent chikungunya virus disease.

Emergent's CHIKV VLP vaccine candidate 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 designation from the European Medicines Agency in September 2019. These designations are designed to facilitate the development or expedite review of medicines that either target an unmet medical need or may demonstrate substantial improvement over available therapy.

About the CHIKV VLP vaccine candidate
Early this year, the company announced two-year persistence data from its Phase 2 safety and immunogenicity study of CHIKV VLP in 415 healthy adults. The CHIKV VLP vaccine candidate continued to demonstrate a favorable safety profile. Two years post-vaccination, SNA responses were 19 times higher than pre-vaccination titers following a single adjuvanted 40 µg dose of the CHIKV VLP vaccine candidate, supporting the persistence of the immune response.[iii] All subjects in the single-dose regimen remained seropositive at their one-year and two-year visits. The vaccine candidate was well-tolerated and no significant vaccine-related safety concerns were identified. The majority of solicited adverse events were mild or moderate in severity and the most frequent was local injection site pain.

About the Chikungunya virus
Chikungunya virus is spread to people by infected mosquitoes. Symptoms include fever, joint pain, headache, muscle pain, joint swelling or rash, with some symptoms lasting months and years. The geographic distribution of CHIKV has expanded to more than 100 countries and territories worldwide.[iv,v]

About Emergent BioSolutions
Emergent BioSolutions is a global life sciences company whose mission is to protect and enhance life. Through our specialty products and contract development and manufacturing services, we are dedicated to providing solutions that address public health threats. Through social responsibility, we aim to build healthier and safer communities. We aspire to deliver peace of mind to our patients and customers so they can focus on what's most important in their lives. In working together, we envision protecting or enhancing 1 billion lives by 2030. For more information, 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 the chikungunya virus, the safety and immunogenicity of the product candidate, executing on our development program and the success of our pivotal trial, 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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[ii] Qian et al. Recent progress on the versatility of virus-like particles. Vaccines (Basel). 2020;8(1):139.

[iii] McCarty J. Long-term Safety and Immunogenicity of an Adjuvanted Chikungunya Virus-Like Particle (CHIKV VLP) Vaccine: Results of a Phase 2, Parallel-Group, Randomized, Double-Blind Trial ISTM 2021

[iv] Schwartz O, Albert ML. Biology and pathogenesis of chikungunya virus. Nat Rev Microbiol. 2010;8(7):491–500.

[v] https://www.cdc.gov/chikungunya/hc/clinicalevaluation.html. Accessed October 13, 2021.

Source: Emergent BioSolutions