Emergent BioSolutions Receives EMA Agreement for Proposed Development Path of Investigational Chikungunya VLP Vaccine Candidate

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GAITHERSBURG, Md., Jan. 13, 2020 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE:EBS) announced that it has received agreement from the European Medicines Agency (EMA) to pursue its proposed development plan for its chikungunya virus virus-like particle (CHIKV VLP) vaccine candidate. The company has proposed conducting a safety and immunogenicity Phase 3 trial using Serum Neutralizing Antibodies (SNA) as an immune correlate of protection to predict clinical benefit of the vaccine candidate.

“Emergent is encouraged by the concurrence we have received from EMA in paving the path for chikungunya vaccine development based on SNA as the surrogate endpoint,” said Abbey Jenkins, senior vice president and vaccines business unit head at Emergent BioSolutions. “As a leading provider of travel health vaccines, Emergent seeks to address the threat posed by this highly debilitating virus by defining a realistic and optimal path to bring to market a much-needed chikungunya vaccine that could potentially serve patients worldwide. We look forward to continuing to work with regulators, including the U.S. Food and Drug Administration (FDA) with whom we had our End-of-Phase 2 meeting last December, as we plan to initiate a pivotal Phase 3 trial this year and define the approach for a post-approval confirmatory efficacy trial.”

The company’s proposed approach of using SNA as a surrogate endpoint is based on evidence from several preclinical, clinical and epidemiological studies. This approach, presented by the company at a recent FDA Vaccines and Related Biological Products Advisory Committee meeting, is based on the premise that the feasibility of a field efficacy trial is complicated by the variable and unpredictable epidemiology of chikungunya disease.

Emergent’s CHIKV VLP vaccine candidate is currently being investigated in a Phase 2 parallel-group, randomized, double-blind, dose-finding study of approximately 430 healthy adults at three U.S. sites. Last November, the company presented updated results indicating that after a single dose, up to 98% of study participants produced a neutralizing antibody response against the chikungunya virus within seven days after vaccination. Further, the immune response persisted for at least one year for subjects who received a single 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. Solicited adverse event profiles were similar across groups and mostly mild or moderate. The most frequent was local injection site pain.

The CHIKV VLP vaccine candidate is licensed from the National Institute of Allergy and Infectious Diseases at the National Institutes of Health. It received FDA Fast Track designation in May 2018 and EMA PRIME designation in September 2019.

About the Chikungunya Virus
Chikungunya virus is spread to people through infected mosquitoes. Symptoms lasting 3-4 weeks include high-grade fever, joint pain, headache, muscle pain, joint swelling, or rash, while chronic arthritis occurs in a minority of patients. Chikungunya outbreaks have occurred in countries in North and South America, Africa, Asia, Europe, and the Indian and Pacific Oceans and can be found in over 70 countries. The chikungunya virus was identified in the Americas on islands in the Caribbean in 2013 and has spread to both North and South America. 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 Virus-like Particle Vaccines
Virus-like particle (VLP) vaccines are multi-protein structures that mimic the organization and conformation of naturally occurring viruses without the viral genome. 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.[1] There is currently no vaccine, VLP or otherwise, to prevent chikungunya virus infection.

About Emergent BioSolutions
As a global life sciences company whose mission is to protect and enhance life, we provide solutions that target public health threats. Through our specialty products and services as well as our social responsibility efforts, we aspire to build healthier, safer communities and deliver peace of mind to our patients and customers so they can focus on what’s most important in their lives. For more information visit 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 our ability to define a realistic and optimal path to bringing to market an approved vaccine to prevent the chikungunya virus that would serve patients worldwide, the effectiveness of our CHIKV VLP vaccine candidate, executing on our chikungunya vaccine development program and the initiation of a pivotal Phase 3 trial this 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.

[1] 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.

Investor Contact:
Robert G. Burrows
Vice President, Investor Relations
240-631-3280
BurrowsR@ebsi.com

Media Contact:
Lynn Kieffer
Vice President, Corporate Communications
240-631-3391
KiefferL@ebsi.com

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