Emergent BioSolutions Presents Positive Immunogenicity Results From Phase 2 Study of Its Investigational Chikungunya VLP Vaccine Candidate

November 22, 2019

GAITHERSBURG, Md., Nov. 22, 2019 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE:EBS) announced updated 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 after the first dose is administered, up to 98% of study participants produced a neutralizing antibody response against the chikungunya virus (CHIKV) within seven days after vaccination. Further, the immune response persisted for at least one year for subjects who received a single dose. The presentation was made at the American Society of Tropical Medicine and Hygiene (ASTMH) annual meeting in Maryland being held November 20 to 24, 2019.

Abbey Jenkins, senior vice president and vaccines business unit head at Emergent BioSolutions, stated, "Emergent is pleased with the positive momentum and progress of our chikungunya vaccine development program. Within the last three months, we have received PRIority MEdicines or PRIME designation from the European Medicines Agency (EMA), provided industry input and expertise at the U.S. Food and Drug Administration (FDA) advisory committee meeting on the development path of chikungunya vaccines, and presented updated interim data indicating that a single dose of our vaccine candidate produced an immune response, which persisted through the study participants' visits at 12 months. There are currently no vaccines or treatments available for chikungunya virus infection and, as a leading provider of travel health vaccines, Emergent is hoping to fill this significant unmet medical need with our CHIKV VLP vaccine once approved. We look forward to continuing to engage with U.S. and European regulators as we prepare to initiate a pivotal trial in 2020."

This Phase 2 parallel-group, randomized, double-blind, dose-finding study involved 415 healthy adults at three U.S. sites. Participants were assigned at random to one of several doses and regimens, including a single dose.

Seroconversion occurred in 74% to 98% of subjects within seven days after one dose, and in all subjects by 28 days after the last dose. Looking specifically at the single-dose regimen, 96% of the single dose volunteers had detectable antibodies within seven days of the vaccination. At the one-year visit, 98% of subjects receiving the single-dose regimen remained sero-positive. Additionally, this arm had the highest Geometric Mean Titer at Days 7, 182, and 365 compared to the other arms, which suggests a durability of inducing high serum neutralizing titers with just a single dose. Subjects in three of the arms will be followed for at least two years to examine persistence of the response.

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.

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.

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 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 our ability to fill the need for an approved vaccine to prevent the chikungunya virus, the effectiveness of the product candidate, executing on our development program 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.

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

---

[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.

Source: Emergent BioSolutions