Emergent BioSolutions Announces Initiation of Phase 1 Study Evaluating Its Universal Influenza Vaccine Candidate

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GAITHERSBURG, Md., Dec. 16, 2021 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE: EBS) today announced the first participant dosed in its phase 1 study, EBS-UFV-001, evaluating the safety, tolerability, and immunogenicity of the company's investigational universal influenza vaccine candidate. This current version of Emergent's universal influenza vaccine candidate contains multiple components intended to induce broad and supra-seasonal immunity against influenza A viruses.

"Emergent remains focused on investing in our diverse portfolio of R&D programs targeting infectious disease and other public health threats," said Kelly Warfield, Ph.D., senior vice president, research and development at Emergent BioSolutions. "Initiating this phase 1 study demonstrates our commitment to advancing our pipeline and our research and development team's scientific prowess to adopt an innovative technology and investigate a potential vaccine candidate for a disease that affects millions every year."

The goal of this single-center, randomized, double blind, placebo-controlled dose-escalation study is to evaluate the safety, tolerability, and immunogenicity of the vaccine candidate at two dose levels and two schedules in 60 healthy adult individuals aged 18 to 45. This phase 1 study, being conducted in Australia, is fully funded by Emergent.

Emergent's universal influenza vaccine candidate is based on a nanoparticle vaccine that self-assembles during production and that displays a cross-reactive hemagglutinin (HA) antigen for influenza virus A groups 1 and 2. The self-assembling HA stabilized stem nanoparticle technology was developed by and licensed from the National Institute of Allergy and Infectious Diseases Vaccine Research Center. Using this technology, a universal influenza vaccine could be designed to confer protection against divergent, constantly evolving strains and subtypes of influenza virus.[i,ii,iii]

For more information on the study, visit clinicaltrials.gov.

About Seasonal Influenza
Seasonal influenza is an acute respiratory infection caused by influenza viruses which circulate in all parts of the world. There are four types of seasonal influenza viruses – types A, B, C, and D. Influenza A and B viruses circulate and cause seasonal epidemics of disease.

Seasonal influenza can be characterized by the sudden onset of fever, cough, headache, muscle and joint pain, severe malaise, sore throat and a runny nose. Most people recover from fever and other symptoms within a week without requiring medical attention. However, influenza can cause severe illness or death especially in people at high risk (*e.g.*, pregnant women, children, the elderly, those with multiple medical comorbidities, and those immunocompromised).

According to the WHO, worldwide, these annual epidemics are estimated to result in 3 to 5 million cases of severe illness, and about 290,000 to 650,000 respiratory deaths.[iv]

About Emergent's Universal Influenza Vaccine
The goal of the final Emergent universal influenza vaccine candidate is to provide broad protection against multiple, divergent, and constantly evolving influenza virus A and B strains, including both seasonal and pandemic threats. The structure-based design of these vaccine components drives immune responses towards broadly cross-reactive and highly conserved antibody-recognized epitopes on the HA protein. The current EBS-UFV-001 phase 1 study is designed to demonstrate safety, tolerability, and immunogenicity of the influenza virus A components of the vaccine candidate with future studies planned to investigate additional components for full coverage against all influenza virus A and B strains.

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 the safety, tolerability and immunogenicity of the product candidate, executing on our development program, the success of our clinical trial, the inducement of broad and supra-seasonal immunity against influenza A, advancing our pipeline and potential solutions to combat influenza A and B, 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. The reader should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. Readers 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 this and other related clinical trials and the overall development program; the timing of and our 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. Readers 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.

[i] Kanekiyo, M. et al. Self-assembling influenza nanoparticle vaccines elicit broadly neutralizing H1N1 antibodies. Nature 499, 102-106 (2013).

[ii] Yassine, H. M. et al. Hemagglutinin-stem nanoparticles generate heterosubtypic influenza protection. Nat Med 21, 1065-1070 (2015).

[iii] https://pubmed.ncbi.nlm.nih.gov/30808695/

[iv] https://www.who.int/news-room/fact-sheets/detail/influenza-(seasonal)

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