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EMERGENT BIOSOLUTIONS INITIATES PHASE 1 CLINICAL STUDY OF ZIKA VIRUS IMMUNE GLOBULIN THERAPEUTIC

 ZIKV-IG granted Fast Track designation by the U.S. Food and Drug Administration

GAITHERSBURG, Md., July 31, 2018 — Emergent BioSolutions Inc. (NYSE:EBS) today announced the initiation of a Phase 1 clinical study to evaluate the safety and pharmacokinetics of ZIKV-IG, the company's anti-Zika virus immune globulin, being developed as a therapeutic intervention against Zika virus disease. ZIKV-IG was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) in December 2017.

"Zika is an important disease with global impact due to its profound effect on the fetus and child-maternal health," said Dr. Laura Saward, senior vice president and antibody therapeutics business unit head at Emergent BioSolutions. "The World Health Organization has stated the urgent need for accelerated research and development for countermeasures for Zika given its potential to cause a public health emergency and the absence of efficacious drugs and vaccines for the disease. Emergent is focused on providing preparedness solutions that address public health threats and emerging infectious diseases. Our program, initiated in 2017, seeks to accelerate development of a Zika-specific immune globulin that leverages our proven platform technology, four decades of patient experience with hyperimmunes, and core competencies in advanced development and manufacturing."

The FDA's fast track process is designed to facilitate the development and expeditious review of products to treat serious conditions and fill an unmet medical need. The main purpose is to get important new drugs to the patient earlier. A drug that receives Fast Track designation could mean more frequent meetings and/or communications between the sponsor and FDA, eligibility for priority review of a Biologics License Application (BLA) if relevant criteria are met, and/or a rolling BLA submission, which allows FDA to review sections of the BLA in advance of receiving the complete submission.

ZIKV-IG is a purified human immunoglobulin containing neutralizing antibodies to Zika virus. It is being developed on the company's human hyperimmune platform, on which several marketed antibody therapeutics have been licensed, including Emergent's Anthrasil® [Anthrax Immune Globulin Intravenous (Human)] and VIG [Vaccinia Immune Globulin Intravenous (Human)] (VIGIV) products.



This Phase 1 double-blind, randomized, placebo-controlled clinical study will enroll approximately 30 healthy volunteers at a single site.

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, intentional, and naturally occurring public health threats. Through our work, we envision protecting and enhancing 50 million lives with our products by 2025. 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, 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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