Emergent BioSolutions' COVID-19 Human Immune Globulin Product Candidate to be Evaluated in NIH-Sponsored Phase 3 Clinical Trial (INSIGHT-012) of Hyperimmune Intravenous Immunoglobulin for Outpatient Treatment of COVID-19

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- NIAID has initiated a Phase 3 clinical trial to evaluate the efficacy and safety of hyperimmune globulin products, including Emergent's COVID-19 Human Immune Globulin (COVID-HIG), for potential treatment of COVID-19 in adult patients at risk of progression to severe disease

GAITHERSBURG, Md., Aug. 25, 2021 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE:EBS) today announced the initiation of a Phase 3 clinical trial that will evaluate its investigational SARS-CoV-2 Immune Globulin Intravenous (Human) (COVID-HIG) plasma-derived therapy as a potential outpatient treatment for patients with coronavirus disease (COVID-19) that are at high risk of progression to severe disease, including adults 55 and older and those 18 and older who are immunocompromised.

The INSIGHT-012 clinical study called "Outpatient Treatment with Anti-Coronavirus Immunoglobulin (OTAC)" is sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). The study will evaluate the safety and efficacy of hyperimmune globulin products derived from plasma of individuals who have recovered from COVID-19 and have developed neutralizing antibodies to SARS-CoV-2, the virus that causes COVID-19. The randomized controlled clinical trial assigns participants to receive infusions of either a placebo or one of two hyperimmune globulin products, including Emergent's COVID-HIG, in addition to standard of care in all groups.

"Emergent is pleased to be working closely with NIAID/ NIH and the Biomedical Advanced Research and Development Authority (BARDA) to potentially fill an unmet need for COVID-19 therapeutics and for use with certain populations such as the immunocompromised or those who cannot receive vaccines," said Dr. Laura Saward, SVP and therapeutics business unit head at Emergent BioSolutions. "Treatment with COVID-HIG earlier in the COVID-19 disease course offers a window of intervention when viral replication is extensive but natural antibody response hasn't been generated yet. This earlier intervention has the potential to improve patient outcomes and keep people out of the hospital. As a polyclonal product with many different types of antibodies, COVID-HIG may also provide additional benefits against variants of concern as demonstrated by *in vitro* testing."

Emergent is one of two companies providing hyperimmune globulin products for the trial, which plans to enroll approximately 800 patients across U.S. and international clinical trial sites. The OTAC investigators will assess whether giving people anti-coronavirus hyperimmune globulin at the onset of COVID-19 symptoms could quickly augment the natural—and possibly delayed—antibody response to SARS-CoV-2, thereby potentially reducing the risk of more serious illness and death.

Emergent's COVID-HIG is being developed as a potential treatment for COVID-19 in the outpatient population and is being funded in whole or in part with federal funds from the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority under contract HHSO100201200004I, task order 75A50120F33006.

For more information about the OTAC trial, visit the posting on clinicaltrials.gov.

About Emergent BioSolutions' SARS-CoV-2 Immune Globulin Intravenous (Human) (COVID-HIG)
Hyperimmune globulin, also referred to as polyclonal antibodies, is a concentrated antibody product derived from the antibody-rich plasma of people who were previously infected with and recovered from an illness, in this case, COVID-19 caused by the virus SARS-CoV-2. In order to produce plasma-derived products, plasma is collected from a pool of human donors and then manufactured, or fractionated, into specialized therapeutic products. COVID-HIG is an investigational product that is not approved by the FDA and its safety and effectiveness have not been established.

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 www.emergentbiosolutions.com. For additional information, visit Emergent's website and follow Emergent 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 ability of COVID-HIG to effectively treat patients with COVID-19, particularly adults 55 and older and immunocompromised individuals, as well as those who cannot receive vaccines; the effectiveness of COVID-HIG against variants; its ability to reduce serious illness and death; and statements regarding planned clinical trials, 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 overall success of the collaboration and planned development programs; our ability to maintain a sufficient level of convalescent plasma; the results of planned clinical trials and the timing of and our ability to obtain and maintain regulatory authorizations for emergency or broader patient use or approvals; 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.

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