Emergent BioSolutions' COVID-19 Human Immune Globulin Product Candidate to be Included in NIH-Sponsored Phase 3 Clinical Trial of Hyperimmune Intravenous Immunoglobulin to Treat COVID-19

October 8, 2020

- NIAID has initiated a Phase 3 clinical trial to evaluate the safety, tolerability, and efficacy of hyperimmune globulin products, including Emergent's COVID-19 Human Immune Globulin (COVID-HIG), as a potential treatment in adult patients hospitalized with COVID-19
- Emergent is planning additional clinical trials to evaluate COVID-HIG for potential use in other patient populations or individuals at high risk of exposure

GAITHERSBURG, Md., Oct. 08, 2020 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE:EBS) today announced the initiation of the Phase 3 clinical trial that will evaluate plasma-derived therapy COVID-HIG as a potential treatment for hospitalized patients with coronavirus disease (COVID-19). The INSIGHT-013 clinical study called "Inpatient Treatment with Anti-Coronavirus Immunoglobulin (ITAC)," 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, tolerability, 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 four hyperimmune globulin products, which includes Emergent's COVID-HIG, with a background therapy of remdesivir in all groups.

"Emergent is proud to continue our partnership with NIAID/ NIH and the Biomedical Advanced Research and Development Authority (BARDA) to advance potential therapeutic solutions for COVID-19 in hospitalized patients," said Dr. Laura Saward, SVP and therapeutics business unit head at Emergent BioSolutions. "We are drawing from decades of experience developing treatments on our well-established hyperimmune platform to address this serious public health threat."

Emergent is one of four companies providing hyperimmune globulin products for the trial, which plans to enroll approximately 500 patients across U.S. and international clinical trial sites. The ITAC investigators will assess whether giving people anti-coronavirus hyperimmune globulin at the onset of COVID-19 symptoms could augment the natural—and possibly delayed—antibody response to SARS-CoV-2, thereby potentially reducing the risk of more serious illness and death. The main goal of the trial is to compare the health status of participants treated with hyperimmune globulin plus remdesivir with participants treated with a placebo plus remdesivir. Remdesivir, an investigational broad-spectrum antiviral, was developed by Gilead Sciences, Inc.

Emergent's COVID-HIG is being developed as a potential treatment for hospitalized patients as well as high-risk, acute symptomatic patients with $14.5 million in funding from BARDA, part of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response. COVID-HIG will also be evaluated as a potential post-exposure prophylaxis (PEP) therapeutic in populations at high risk of exposure to SARS-CoV-2, such as front-line health care workers and military service members, with funding from the U.S. Department of Defense. The Investigational New Drug (IND) application to enable use of COVID-HIG in the ITAC study was submitted to the U.S. Food and Drug Administration (FDA) and subsequently cleared in August. The IND supports use of COVID-HIG in NIAID's current ITAC trial and will also support the additional treatment and PEP indications to be investigated in future clinical studies.

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

About Hyperimmune Globulin
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.

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. Find us on LinkedIn and follow us on Twitter @emergentbiosolu and Instagram @life_at_emergent.

Emergent's Response to COVID-19
Emergent BioSolutions is deploying its decades of experience in vaccine and hyperimmune development and manufacturing, as well as its molecule-to-market contract development and manufacturing (CDMO) services to provide comprehensive medical countermeasure solutions in response to the COVID-19 pandemic.

Using its established hyperimmune platforms, Emergent is developing two investigational plasma-based treatments - COVID-19 Human Immune Globulin (COVID-HIG) and COVID-Equine Immune Globulin (COVID-EIG). COVID-HIG is being developed as a human plasma-derived therapy candidate with $14.5 million in HHS funding and will be evaluated in two studies, inclusive of INSIGHT-13 (ITAC), of the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, for potential treatment of COVID-19 in severe hospitalized and high-risk patients. With $34.6 million in funding from the Department of Defense's Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense, and in collaboration with the Mount Sinai Health System and ImmunoTek Bio Centers, COVID-HIG will also be evaluated for post-exposure prophylaxis in populations at high risk of COVID-19, such as front-line health care workers and the military. COVID-EIG is being developed as an equine plasma-derived therapy candidate for potential treatment of severe disease in humans. Both candidates are anticipated to be in clinical studies in 2020 and 2021. These investigational products are not approved by the U.S. Food and Drug Administration and their safety and effectiveness have not been established.

Emergent is deploying its CDMO capabilities, capacities, and expertise to support the U.S. government's Operation Warp Speed to pave the way for innovators to advance COVID-19 programs. The company is working with four innovators to develop and manufacture COVID-19 vaccine candidates. For the COVID-19 vaccine response, Emergent's integrated CDMO network provides development services from its Gaithersburg facility, drug substance manufacturing at its Baltimore Bayview facility, and drug product manufacturing at its Baltimore Camden and Rockville facilities, all in Maryland.

For 22 years Emergent has focused on advancing public health, and its multi-pronged approach to tackling COVID-19 demonstrates its commitment to its mission – to protect and enhance life.

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 hospitalized patients with COVID-19, as well as high-risk, acute symptomatic patients and to become an effective PEP therapeutic for groups at high risk of developing COVID-19, and the ability of COVID-EIG to treat severe disease in humans, as well as 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. 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 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. 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.

Media Contact:
Miko B. Neri
Senior Director, Global Communications & Public Affairs
240-631-3392
nerim@ebsi.com

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

Source: Emergent BioSolutions