Emergent BioSolutions and Mount Sinai Health System Announce Initiation of DOD-Funded Clinical Program to Evaluate COVID-19 Human Hyperimmune Globulin (COVID-HIG) Product Candidate for Prophylaxis

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GAITHERSBURG, Md. and NEW YORK, Dec. 29, 2020 (GLOBE NEWSWIRE) -- Emergent BioSolutions (NYSE: EBS) and Mount Sinai Health System today announced initiation of the clinical program to evaluate Emergent's COVID-19 Human Hyperimmune Globulin (COVID-HIG) product candidate in the first of two Phase 1 studies to support its use for potential post-exposure prophylaxis in individuals at high risk of exposure to SARS-CoV-2, the virus that causes COVID-19, such as front-line health care workers and military personnel.

The first study will evaluate safety and pharmacokinetics of three dose levels administered as a single or repeat IV dose in healthy adults. The second study, once initiated, will evaluate safety, pharmacokinetics, and pharmacodynamics of two dose levels administered as a single IV dose to adults with SARS-CoV-2 infection, whether asymptomatic or with mild COVID-19.

"Emergent is pleased to partner with Mount Sinai, a leader in clinical research to combat COVID-19, and expand the clinical evaluation of COVID-HIG," said Dr. Laura Saward, SVP and Therapeutics Business Unit Head at Emergent BioSolutions. "This innovative public-private partnership represented by government, industry, and healthcare providers has the potential to make a significant impact benefiting our front-line health care workers and others who protect us."

"Mount Sinai is thrilled to be initiating research into potentially important therapeutics against COVID-19," said Judith A. Aberg, MD, Chief of the Division of Infectious Disease at Mount Sinai Health System. "Our team has developed a great scientific partnership with Emergent and looks forward to performing this important research."

The existing plasma collection capabilities at Mount Sinai established through its collaboration with Emergent and ImmunoTek Bio Centers has enabled ongoing plasma collection from recovered donors to support the development and manufacture of COVID-HIG for evaluation in clinical trials. The clinical research program, including a planned Phase 2 study, is designed to assess whether prophylaxis with COVID-HIG could help protect individuals following high-risk exposure to SARS-CoV-2.

The U.S. Department of Defense's (DOD) Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) has provided $34.6 million in funding in support of this program.

"The DOD looks forward to reviewing the results of this important clinical trial and is pleased to support this initiative, which should enhance the nation's rapid response to COVID-19," said Douglas Bryce, the DOD's Joint Program Executive Officer for CBRND. "Working together through public-private partnerships harnesses expertise from government, industry, and academia, increasing our chances of developing safe and effective medical countermeasures for this, and other biological threats."

Advancing COVID-HIG With U.S. Government Support
In addition to receiving DOD funding to advance a post-exposure prophylaxis indication for COVID-HIG, Emergent was awarded $14.5 million in April 2020 by the U.S. Department of Health and Human Services (HHS) to develop COVID-HIG as a potential treatment for COVID-19. Emergent's proprietary COVID-HIG product candidate is also being evaluated in a Phase 3 clinical study initiated in October 2020 by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), as a potential treatment in hospitalized patients. Mount Sinai serves as a study site.

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 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 hyperimmune globulin manufactured from plasma of individuals with elevated levels of antibodies to SARS-CoV-2. COVID-HIG is not approved by the U.S. Food and Drug Administration and its safety and effectiveness have not been established.

About the Mount Sinai Health System
The Mount Sinai Health System is New York City's largest academic medical system, encompassing eight hospitals, a leading medical school, and a vast network of ambulatory practices throughout the greater New York region. Mount Sinai is a national and international source of unrivaled education, translational research and discovery, and collaborative clinical leadership ensuring that we deliver the highest quality care—from prevention to treatment of the most serious and complex human diseases. The Health System includes more than 7,200 physicians and features a robust and continually expanding network of multispecialty services, including more than 400 ambulatory practice locations throughout the five boroughs of New York City, Westchester, and Long Island. The Mount Sinai Hospital is ranked No. 14 on *U.S. News & World Report's* "Honor Roll" of the Top 20 Best Hospitals in the country and the Icahn School of Medicine as one of the Top 20 Best Medical Schools in country. Mount Sinai Health System hospitals are consistently ranked regionally by specialty and our physicians in the top 1% of all physicians nationally by *U.S. News & World Report*.

For more information, visit https://www.mountsinai.org or find Mount Sinai on Facebook, Twitter and YouTube.

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 additional information, visit our website and follow us on LinkedIn, Twitter and Instagram.

Emergent BioSolutions 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 whether prophylaxis with COVID-HIG could protect individuals following high-risk exposure to SARS-CoV-2 and significantly benefit front-line healthcare workers and military personnel and the use of COVID-HIG as a potential safe and effective treatment in hospitalized patients 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 collaboration and planned development programs; the availability of antibody-rich plasma; the results of clinical trials; the timing of and our ability to obtain and maintain FDA approval or authorization for emergency or broader patient use of COVID-HIG; 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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