Emergent BioSolutions Partners with U.S. Government for Comprehensive Response to Expedite Development of Plasma-Derived Therapy for COVID-19

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- BARDA to provide $14.5 million in funding to support development of COVID-Human Immune Globulin (COVID-HIG), a human plasma-derived therapy candidate being developed as a potential treatment for COVID-19 in severe hospitalized and high-risk patients
- NIAID to include COVID-HIG product candidate in one of its clinical studies for assessment of treatments for COVID-19 upon availability of clinical material
- Emergent will seek a path forward with the FDA for the development of COVID-HIG and possible use under Emergency Use Authorization (EUA)

GAITHERSBURG, Md., April 02, 2020 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE:EBS) announced today that it has entered into a formal partnership with the U.S. government to expedite development of a plasma-derived therapy for patients with coronavirus disease 2019 (COVID-19). Emergent has received $14.5 million from the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health & Human Services (HHS), in support of its COVID-HIG program, one of two hyperimmune development programs announced by Emergent in March.

COVID-HIG is a candidate human hyperimmune product being developed as a potential treatment for COVID-19 in severe hospitalized patients and high-risk, acute symptomatic patients to prevent progression to severe symptoms. COVID-HIG will be manufactured using plasma donations from people who have recovered from COVID-19 with antibodies to SARS-CoV-2.

Robert G. Kramer Sr., president and CEO of Emergent BioSolutions, stated, “In the current pandemic scenario where no preventative or therapeutic options for COVID-19 are available, public-private partnerships such as this are essential to the rapid development of medical interventions. Aside from deploying our HHS-partnered Center for Innovation in Development and Manufacturing (CIADM) to help companies advance COVID-19 vaccine candidates through manufacturing, today’s announcement of BARDA’s funding is a testament to the strength and reliability of our proven hyperimmune platform, which has a successful history of enabling us to produce treatments for serious public health threats. With more than 40 years of experience with plasma-derived therapies, Emergent is committed to the goal of getting COVID-HIG to patients as early as possible, with a potential broader reach under Emergency Use Authorization, and the availability of a commercial supply.”

“Treatments for hospitalized COVID-19 patients are urgently needed to save lives in this severe pandemic,” said BARDA Director Rick Bright, Ph.D. “We are working with partners in industry and across the government, including engaging long-standing CIADM partners, to make safe, effective treatments available as quickly as possible.”

Emergent and the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), have agreed to incorporate the company’s COVID-HIG product candidate into one of NIAID’s clinical studies for assessment of treatments for COVID-19 once clinical material is available, and the study begins. Emergent has already initiated plasma screening and collection of human plasma with antibodies to SARS-CoV-2 that will be further purified and concentrated through manufacturing of COVID-HIG.

“We are proud to continue our partnership with the U.S. government to lay the foundation of our near-term response plan. Our mutual objective is to save lives and Emergent is fully committed to working closely with BARDA, NIH/NIAID, the Food and Drug Administration (FDA), and other key agencies to stay aligned on this common goal,” said Dr. Laura Saward, senior vice president and therapeutics business unit head at Emergent BioSolutions. “COVID-HIG will leverage the platform that was established in partnership with BARDA through their investment in our treatments for anthrax and smallpox vaccine complications, and it provides a sustainable capability for responding to emerging infectious diseases such as COVID-19.”

Expertise in Hyperimmune Therapeutic Development and Manufacturing
Hyperimmunes are polyclonal antibody therapeutics that are manufactured from plasma and leverage the natural immune response in humans or animals. COVID-HIG has the potential to serve as both a treatment for severe hospitalized patients and protection for at-risk individuals. In parallel and separate from the COVID-HIG development effort with BARDA, COVID-EIG, manufactured from the plasma of immunized horses with antibodies to SARS-CoV-2, will be developed by the company as a potential treatment for severe hospitalized patients.

COVID-HIG will be developed on Emergent’s human hyperimmune platform and COVID-EIG will be developed on the equine hyperimmune platform. These hyperimmune platforms and related in-house manufacturing infrastructure support several products approved by the FDA, including the company’s treatments for smallpox vaccine complications, VIG [Vaccinia Immune Globulin Intravenous (Human)] (VIGIV), for anthrax, Anthrasil ® [Anthrax Immune Globulin Intravenous (Human)], and for botulism, BAT® [Botulism Antitoxin Heptavalent (A, B, C, D, E, F, G) - (Equine)].

Expertise in Vaccine Development and Manufacturing
Emergent’s multi-faceted response to COVID-19 includes the rapid deployment of its molecule-to-market contract development and manufacturing (CDMO) services. The company recently announced collaborations to develop and manufacture two COVID-19 vaccine candidates utilizing its integrated network, which includes its Baltimore Bayview CIADM. The Baltimore Bayview CIADM offers the capacity to produce tens to hundreds of millions of doses of vaccine annually depending on the platform technology used. Emergent continues to be in discussions with fellow innovators about how the company can help advance their development and manufacturing programs.

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.

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 our ability to develop potential treatments for coronavirus disease in severe hospitalized and high-risk, acute symptomatic patients (using our existing platforms) to prevent progression to severe symptoms and expedite development of plasma-derived therapy by seeking a path forward for potential use of COVID-HIG under Emergency Use Authorization (EUA) 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 programs; the timing of and our ability to obtain and maintain regulatory authorizations (including EUA) or approvals for related product candidates; 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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