Emergent BioSolutions Announces Topline Data from NIAID Phase 3 ITAC Trial (INSIGHT-013) Evaluating Immunoglobulins as a Treatment for Hospitalized Patients with COVID-19

April 2, 2021

GAITHERSBURG, Md., April 02, 2021 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE:EBS) today provided an update on the evaluation of its investigational SARS-CoV-2 Immune Globulin Intravenous (Human) (COVID-HIG) for the treatment of hospitalized patients with COVID-19. The Phase 3 Inpatient Treatment with Anti-Coronavirus Immunoglobulin (ITAC) trial, also known as INSIGHT-013, sponsored and supported by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), assessed the safety and efficacy of four immunoglobulin candidates plus standard of care versus placebo plus standard of care in hospitalized patients with COVID-19. Topline data from the ITAC trial demonstrated that the addition of anti-SARS-CoV-2 hyperimmunoglobulin to standard of care, inclusive of remdesivir, for hospitalized adult COVID-19 patients with symptoms for less than 12 days did not provide clinical benefit when compared to standard of care plus placebo. There were no serious safety concerns identified.

“While we are disappointed by these data in hospitalized patients where there remains a high unmet need, we recognize that, similar to other antibody-based therapies, intervention with COVID-HIG earlier in the disease course may be necessary to impact COVID-19 in patients,” said Dr. Laura Saward, SVP and therapeutics business unit head at Emergent BioSolutions. “Emergent will continue to explore COVID-HIG as a treatment in ongoing clinical trials. The public-private partnership with NIAID and the Biomedical Advanced Research and Development Authority (BARDA) has been important to generate data on the COVID-HIG investigational product. We also would like to thank all study participants, sites, and investigators across the globe who contributed to this effort.”

COVID-HIG is also being developed as a potential treatment for outpatients at high risk of progression to severe disease with funding from BARDA. It is also being supported with funding from the U.S. Department of Defense.

This project has been 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.

About the ITAC Trial
The Phase 3 Inpatient Treatment with Anti-Coronavirus Immunoglobulin (ITAC) clinical trial was a global, multi-center, double-blind, placebo-controlled, randomized trial sponsored and funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). It was designed to test the safety, tolerability and efficacy of a combination treatment regimen for coronavirus disease 2019 (COVID-19) consisting of the antiviral remdesivir along with an anti-coronavirus hyperimmune intravenous immunoglobulin (H-Ig), which contains a highly concentrated solution of antibodies that neutralize SARS-CoV-2. The antibodies in the H-Ig come from the liquid portion of blood, or plasma, donated by healthy people who have recovered from COVID-19.

Through the NIAID-funded INSIGHT network, the study team enrolled nearly 600 adult patients at 63 sites in the United States and 10 other countries on five continents. Volunteers were eligible for the trial if they had been hospitalized for COVID-19 and had symptoms for 12 days or fewer without life-threatening organ dysfunction or end-organ failure. Four companies provided investigational H-Ig materials for the trial, including CSL Behring and Takeda on behalf of the CoVIg-19 Plasma Alliance, as well as Emergent BioSolutions and Grifols. Further information about the ITAC trial is available at ClinicalTrials.gov under study identifier NCT04546581.

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.

Emergent’s Response to COVID-19
In addition to leveraging its established hyperimmune platform to develop COVID-HIG, Emergent is deploying its molecule-to-market contract development and manufacturing (CDMO) capabilities, capacities, and expertise to help governments/non-government organizations and pharmaceutical/biotechnology partners advance their COVID-19 programs. The company has engaged in nine collaborations to develop and manufacture COVID-19 vaccine and therapeutic candidates. For the COVID-19 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, Rockville, and Winnipeg facilities.

For more than 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, 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.

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Source: Emergent BioSolutions