Emergent BioSolutions Signs Agreement with AstraZeneca to Expand Manufacturing for COVID-19 Vaccine Candidate

July 27, 2020

- Emergent will provide contract development and manufacturing services beginning in 2020 to produce drug substance at large scale for commercial supply
- Agreement is valued at approximately $174 million through 2021 and brings the total AstraZeneca commitment to $261 million
- Parties may enter into additional commercial manufacturing commitments as the candidate progresses over three years through Emergent's flexible capacity deployment model

GAITHERSBURG, Md., July 27, 2020 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE:EBS) today announced that it has signed an agreement to provide contract development and manufacturing (CDMO) services for large-scale commercial drug substance manufacturing for AstraZeneca's COVID-19 vaccine candidate, AZD1222. The agreement is valued at approximately $174 million through 2021 and follows an $87 million contract in June for development services, performance and process qualification, raw materials and an initial capacity reservation.

"Emergent is driven by our desire to advance solutions that will make an impact on this pandemic," said Robert G. Kramer Sr., president and chief executive officer of Emergent BioSolutions. "Sharing a passion for science, we are encouraged by AstraZeneca's investigational COVID-19 vaccine and look forward to supporting its continued progress."

The adenovirus vector-based vaccine candidate, AZD1222, was co-invented by the University of Oxford and its spin-out company, Vaccitech, and licensed by AstraZeneca. The vaccine candidate is currently in clinical trials. It is one of the candidates funded and supported by Operation Warp Speed (OWS), the U.S. government's program to accelerate the development, manufacturing, and distribution of COVID-19 medical countermeasures that aims to have substantial quantities of a safe and effective vaccine available.

Syed T. Husain, senior vice president and CDMO business unit head at Emergent, stated, "As COVID-19 vaccine candidates progress through the pipeline, Emergent stands ready alongside leading innovators to rapidly deploy our CDMO services to help meet the substantial demand for a vaccine – anchored on our foundational expertise in development and manufacturing and propelled by our commitment to our mission – to protect and enhance life."

This agreement follows and is in addition to the landmark public-private CDMO partnership between Emergent and the Biomedical Advanced Research and Development Authority (BARDA) announced in June to pave the way for OWS high-priority innovators.

Activities under this agreement will be performed at Emergent's Baltimore Bayview facility, where certain manufacturing capacity reserved by BARDA through the CDMO task order issued to Emergent under OWS will be used. Emergent's Baltimore Bayview facility is a designated Center for Innovation in Advanced Development and Manufacturing (CIADM) by the U.S. Department of Health and Human Services (HHS) designed for rapid manufacturing of large quantities of vaccines and treatments during public health emergencies.

The CIADM has unique capabilities across four independent suites to produce at clinical scale to get candidates rapidly into the clinic, while at the same time scaling up to enable large-scale manufacturing to up to 4000L to prepare for production of commercial volumes to meet customer demand. The CIADM has the capacity to produce tens to hundreds of millions of doses of vaccine on an annual basis, based upon the platform technology being used.

Financial Considerations
The company will provide an update to its 2020 financial outlook incorporating expectations related to this agreement and any other relevant information when it reports its second quarter financial results on July 30, 2020.

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-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 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 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 Phase 2 clinical studies in 2020. 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 our ability to produce viable COVID-19 vaccine candidates at the prescribed scale and on the anticipated timeline and pave their potential pathway to licensure, the total value and anticipated duration of activities under the announced AstraZeneca contract as well as the negotiation of any further commitments or contracts related to the collaboration and deployment of capacity toward future commercial manufacturing, 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 ability to obtain and maintain regulatory approvals for the 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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