Emergent BioSolutions Receives U.S. FDA Approval for Drug Product Manufacturing of raxibacumab at its Winnipeg, Canada Site

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GAITHERSBURG, Md., Dec. 12, 2025 (GLOBE NEWSWIRE) -- Emergent BioSolutions (NYSE: EBS) today announced that the U.S. Food and Drug Administration (FDA) has approved its supplemental Biologics License Application (sBLA) for its Winnipeg, Canada facility to be added as the drug product manufacturing and testing site for raxibacumab, a monoclonal antibody for the treatment and prophylaxis of inhalational anthrax.

"We are pleased with the U.S. FDA approval of our sBLA for raxibacumab manufacturing at Emergent's USMCA-compliant site in Winnipeg," Joe Papa, president and CEO, Emergent. "This regulatory action further supports the advancement of our multi-year transformation strategy by building a flexible, streamlined and customer-focused manufacturing network. We will continue to take actions that progress our key turnaround priorities toward driving long-term and sustainable growth."

This approval follows Emergent's May 2024 announcement of a new operational plan to consolidate its manufacturing sites and concentrate operations in Winnipeg, Canada and Lansing, Michigan as part of its multi-year turnaround and transformation strategy. Emergent's Winnipeg facility has over 45 years of experience developing and manufacturing preclinical to commercial therapeutics. Through this facility, Emergent maintains drug substance, fill/finish, and analytical testing capabilities to support the manufacturing of its medical countermeasures portfolio, as well as capacity for strategic manufacturing partnerships.

Indication and Select Important Safety Information for raxibacumab Injection

Indication
raxibacumab is indicated for the treatment of adult and pediatric patients with inhalational anthrax due to *Bacillus anthracis* in combination with appropriate antibacterial drugs, and for prophylaxis of inhalational anthrax when alternative therapies are not available or are not appropriate.

Limitations of Use: The effectiveness of raxibacumab is based solely on efficacy studies in animal models of inhalational anthrax. There have been no studies of raxibacumab in the pediatric population; dosing in pediatric patients was derived using an extrapolation approach.

Important Safety Information

Warning: Hypersensitivity and Anaphylaxis
Hypersensitivity reactions, including anaphylaxis, have been reported during or after the administration of raxibacumab by intravenous infusion. Administer raxibacumab by intravenous infusion in monitored settings where appropriate equipment, medication (including epinephrine), and personnel trained in the management of hypersensitivity, anaphylaxis, and shock are available.

Adverse Reactions: Common adverse reactions in healthy adult subjects (≥1.5%) were injection site reaction, erythema and pain, headache, rash, pain in extremity, pruritus, and somnolence.

To report Suspected Adverse Reactions, contact Emergent BioSolutions at 1-800-768-2304 or medicalinformation@ebsi.com; or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
Please see the full Prescribing Information for raxibacumab for additional safety information.

About Emergent BioSolutions
At Emergent, our mission is to protect and save lives. For over 25 years, we've been at work preparing those entrusted with protecting public health. We deliver protective and life-saving solutions for health threats like smallpox, mpox, botulism, Ebola, anthrax and opioid overdose emergencies. To learn more about how we help prepare communities around the world for today's health challenges and tomorrow's threats, visit our website and follow us on LinkedIn, X, Instagram, Apple Podcasts and Spotify.

Safe Harbor Statement
This communication includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical fact, including statements regarding raxibacumab manufacturing at our Winnipeg manufacturing site, capacity for strategic manufacturing partnerships, our multi-year transformation strategy, and actions to progress our key turnaround priorities are forward-looking statements. We generally identify forward-looking statements by using words like "anticipate," "believe," "continue," "could," "estimate," "expect," "forecast," "future," "goal," "intend," "may," "plan," "position," "possible," "potential," "predict," "project," "should," "target," "will," "would," and similar expressions or variations thereof, or the negative thereof, but these terms are not the exclusive means of identifying such statements. Forward-looking statements are based on our current intentions, beliefs and expectations regarding future events based on information that is currently available. We cannot guarantee that any forward-looking statement will be accurate. Readers should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. Readers are, therefore, cautioned not to place undue reliance on any forward-looking statements. Any forward-looking statement speaks only as of the date of this communication and, except as required by law, we do not undertake any obligation to update any forward-looking statement to reflect new information, events or circumstances.

There are a number of important factors that could cause our actual results to differ materially from those indicated by any forward-looking statements. Readers should consider this cautionary statement, as well as the risk factors and other disclosures included in our periodic reports filed with the Securities and Exchange Commission, when evaluating our forward-looking statements.

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