Emergent BioSolutions Receives U.S. FDA Approval of CYFENDUS™ (Anthrax Vaccine Adsorbed, Adjuvanted), previously known as AV7909, a Two-Dose Anthrax Vaccine for Post-Exposure Prophylaxis Use

July 20, 2023

- Emergent has been delivering CYFENDUS™ vaccine to the U.S. Department of Health and Human Services since 2019, under pre-Emergency Use Authorization status, and will continue to work with the U.S. government to transition to post-approval procurement

GAITHERSBURG, Md., July 20, 2023 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE:EBS) announced today that the U.S. Food and Drug Administration (FDA) has approved CYFENDUS™ (Anthrax Vaccine Adsorbed, Adjuvanted), previously known as AV7909, for post-exposure prophylaxis of disease following suspected or confirmed exposure to *Bacillus anthracis* in persons 18 through 65 years of age when administered in conjunction with recommended antibacterial drugs. The efficacy of CYFENDUS™ vaccine for post-exposure prophylaxis is based solely on studies in animal models of inhalational anthrax.

"The approval of CYFENDUS™ vaccine is symbolic of Emergent's longstanding partnership with the U.S. government and our shared commitment to helping protect public health," said Dr. Kelly Warfield, Emergent's senior vice president, science and development. "The 20-year journey from early development to approval is a major milestone that attests to Emergent's scientific and technical prowess and partnering capabilities. We are grateful for the yearslong collaboration with the Biomedical Advanced Research and Development Authority (BARDA) and early support from the Defense Advanced Research Projects Agency (DARPA) and the National Institute of Allergy and Infectious Diseases (NIAID). Congratulations to the Emergent team and all our partners for advancing this product to approval."

"CYFENDUS™ vaccine is a component of the U.S. government's preparedness efforts against anthrax, which remains a high-priority national security threat due to its ability to be easily disseminated, lethality, and potential for major public health impact," said Paul Williams, Emergent's senior vice president, products business. "The approval of the CYFENDUS™ vaccine demonstrates what effective public-private partnerships can achieve for national security. Emergent will continue to work closely with the U.S. government to transition this product to post-approval procurement while ensuring an uninterrupted supply of this important vaccine."

CYFENDUS™ vaccine is comprised of Anthrax Vaccine Adsorbed (AVA) and an additional adjuvant. It has been demonstrated that by using an additional adjuvant, two doses administered over 14 days elicit protective levels of immune response, which can be especially important in response to a large-scale public health emergency involving anthrax. In December 2018, CYFENDUS™ vaccine was the subject of a pre-emergency use authorization package submitted to the FDA. The following year, the U.S. government began procuring this product for national preparedness efforts.

In addition to the CYFENDUS™ vaccine, Emergent's anthrax franchise includes the BioThrax® vaccine, which will continue to serve a critical purpose, as well as two treatments, Anthrasil® [Anthrax Immune Globulin Intravenous (human)], a polyclonal antibody therapeutic, and raxibacumab, a monoclonal antibody therapeutic.

The FDA approval of CYFENDUS™ vaccine is based on data from a series of studies supported by the U.S. government and conducted by Emergent, including:

- a pivotal Phase 3 clinical study that evaluated the lot consistency, immunogenicity, and safety of the vaccine following a two-dose schedule administered intramuscularly in healthy adults,
- a Phase 2 study that evaluated non-interference between the vaccine and antibacterial drugs approved for post-exposure prophylaxis of anthrax disease, and
- non-clinical studies that assessed protective efficacy of the vaccine against lethal challenge with anthrax spores and helped identify neutralizing antibody levels associated with protection against disease.

The Biologics License Application submission and attainment of product licensure were completed under contract number HHSO100201600030C for the advanced development and delivery of CYFENDUS™ vaccine, funded by BARDA, within the Administration for Strategic Preparedness and Response in the U.S. Department of Health and Human Services. Early-stage development funding was also provided by NIAID, part of the National Institutes of Health, and DARPA of the U.S. Department of Defense.

About CYFENDUS™ (Anthrax Vaccine Adsorbed, Adjuvanted)

Indication

CYFENDUS™ (Anthrax Vaccine Absorbed, Adjuvanted) is a vaccine indicated for post-exposure prophylaxis of anthrax disease following suspected or confirmed exposure to *Bacillus anthracis* in persons 18 through 65 years of age when given with recommended antibacterial drugs.

The efficacy of CYFENDUS™ vaccine for post-exposure prophylaxis (PEP) is based solely on studies in animal models of inhalational anthrax.

Important Safety Information

Contraindication: Do not take CYFENDUS™ vaccine if you are allergic to CYFENDUS™ vaccine, BioThrax® (Anthrax Vaccine Adsorbed) or any ingredient of the vaccine.

Allergic reactions: Appropriate medical treatment and supervision must be available after receiving CYFENDUS™ vaccine to manage possible serious allergic reactions. Get medical help right away if you have any symptoms of a serious allergic reaction.

Altered Immunocompetence: Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished immune response to CYFENDUS™ vaccine.

Pregnancy: CYFENDUS™ vaccine can cause fetal harm when administered to a pregnant individual. Before getting CYFENDUS™ vaccine, tell your healthcare provider if you may be pregnant, plan to get pregnant soon, or are nursing a baby.

Adverse reactions: The most common adverse reactions reported were tenderness, pain, warmth, itching, swelling, redness, bruising, arm motion limitations, muscle aches, tiredness, headache, and fever.

U.S. Prescribing Information
The full Prescribing Information for CYFENDUS™ vaccine can be found here. If it is not currently available via this link, it will be visible as soon as possible as the company works to finalize the document. Please check back for the full information shortly.

About Emergent BioSolutions
At Emergent, our mission is to protect and enhance life. For over 20 years, we've been at work defending people from things we hope will never happen—so we are prepared, just in case they ever do. We provide solutions for complex and urgent public health threats through a portfolio of vaccines and therapeutics that we develop and manufacture for governments and consumers. We also offer a range of integrated contract development and manufacturing services for pharmaceutical and biotechnology customers. To learn more about how we plan to protect or enhance 1 billion lives by 2030, visit our website and follow us on LinkedIn, Twitter, and Instagram.

Safe Harbor Statement
This press release 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 the development, availability, and government procurement of CYFENDUS ™ vaccine and the continued development of Emergent's anthrax franchise, are forward-looking statements. We generally identify forward-looking statements by using words like "anticipate," "believe," "continue," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "should," "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. 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 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. Readers should consider this cautionary statement, as well as the risk factors identified in our periodic reports filed with the U.S. Securities and Exchange Commission, when evaluating our forward-looking statements.

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