SIGA Technologies Announces Department of Defense Increases Funding to Develop Post-Exposure Prophylactic Indication for TPOXX®

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NEW YORK, June 15, 2020 (GLOBE NEWSWIRE) -- SIGA Technologies, Inc. (SIGA) (NASDAQ: SIGA), a commercial-stage pharmaceutical company focused on the health security market, today announced that the United States Department of Defense (DoD), via the Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense's (JPEO-CBRND) Joint Project Manager for Chemical, Biological, Radiological, and Nuclear Medical (JPM CBRN Medical), has increased research and development funding to approximately $23 million in connection with the DoD contract to support work necessary to gain a potential label expansion from the U.S. Food and Drug Administration (FDA) for TPOXX® (tecovirimat) for Post-Exposure Prophylaxis (PEP) in addition to the current approved labeling for the treatment of smallpox.

The use of TPOXX for PEP could provide significant potential benefit in the event of a smallpox pandemic or outbreak. While vaccines would play an important role in containing the spread of smallpox, they are only effective if administered prior to infection or no later than four days after infection. However, symptoms of smallpox do not typically appear until approximately 14 days post-infection, and there is currently no diagnostic test to determine infection prior to symptom onset. Given the uncertainty of an individual's infection status in that two-week period, and the highly contagious nature of smallpox, the administration of a vaccine in combination with TPOXX could be an important strategy for reducing morbidity and mortality in a smallpox outbreak. Dosing of TPOXX in the PEP indication is expected to be 28 days rather than the 14-day dosing currently recommended for its use in treating patients with active smallpox infections. This would increase the amount of TPOXX used for each exposed person compared with each infected person.

"During our FDA Advisory Committee meeting in May 2018, several committee members emphasized the importance of evaluating the potential use of TPOXX not only to treat smallpox symptomatic infection, but also to treat patients with known smallpox exposure who have not yet developed symptoms," said Dr. Phil Gomez, CEO of SIGA. "An expansion of the TPOXX label to include its use for PEP would provide greater flexibility to deliver TPOXX to those who might benefit from treatment during a potential outbreak. The recent search for prophylactic agents that could be used for PEP in patients with known exposure to the virus that causes COVID-19 underscores the importance of being able to prevent infection in at-risk individuals. We are pleased to be working with DoD on important studies for a PEP indication that could address similar situations that would arise in the event of a smallpox outbreak."

ABOUT SIGA TECHNOLOGIES, INC. and TPOXX®

SIGA Technologies, Inc. is a commercial-stage pharmaceutical company focused on the health security market. Health security comprises countermeasures for biological, chemical, radiological and nuclear attacks (biodefense market), vaccines and therapies for emerging infectious diseases, and health preparedness. Our lead product is TPOXX®, also known as tecovirimat and ST-246®, an orally administered and IV formulation antiviral drug for the treatment of human smallpox disease caused by variola virus. TPOXX is a novel small-molecule drug and the US government maintains a stockpile of 1.7 million courses in the Strategic National Stockpile under Project BioShield. The oral formulation of TPOXX was approved by the FDA for the treatment of smallpox in 2018. The full label is here: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=fce826ab-4d6a-4139-a2ee-a304a913a253. In September 2018, SIGA signed a contract potentially worth more than $600 million with the Biomedical Advanced Research and Development Authority (BARDA), part of the office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services, for additional procurement and development related to both oral and intravenous formulations of TPOXX.

Recently, SIGA announced in May 2020 that BARDA exercised an option under the 2018 Contract for delivery of approximately 363,000 courses or oral TPOXX as SIGA continues to replenish the U.S. government's stockpile of its smallpox antiviral treatment.

For more information about SIGA, please visit www.siga.com.

About the JPEO-CBRND

The Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense is the Joint Service's lead for development, acquisition, fielding and life-cycle support of chemical, biological, radiological, and nuclear defense equipment and medical countermeasures. As an effective acquisition program, the JPEO-CBRND puts capable and supportable systems in the hands of the service members and first responders, when and where it is needed, at an affordable price. Our vision is a resilient Joint Force, enabled to fight and win unencumbered by a chemical, biological, radiological, or nuclear environment, championed by innovative and state-of-the-art solutions.

About the JPM CBRN Medical

The Joint Project Manager for Chemical, Biological, Radiological, and Nuclear Medical (JPM CBRN Medical), a component of the U.S. Department of Defense's Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense (JPEO-CBRND), aims to provide U.S. military forces and the nation with safe, effective, and innovative medical solutions to counter chemical, biological, radiological, and nuclear threats. The JPM

CBRN Medical facilitates the advanced development and acquisition of medical countermeasures and systems to enhance the nation’s biodefense response capability.

About Smallpox[1]

Smallpox is a contagious, disfiguring and often deadly disease that has affected humans for thousands of years. Naturally-occurring smallpox was eradicated worldwide by 1980, the result of an unprecedented global immunization campaign. Samples of smallpox virus have been kept for research purposes. This has led to concerns that smallpox could someday be used as a biological warfare agent. A vaccine can prevent smallpox, but the risk of the current vaccine's side effects is too high to justify routine vaccination for people at low risk of exposure to the smallpox virus.

FORWARD-LOOKING STATEMENTS

This press release contains certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Such forward-looking statements are subject to various known and unknown risks and uncertainties, and SIGA cautions you that any forward-looking information provided by or on behalf of SIGA is not a guarantee of future performance. More detailed information about SIGA and risk factors that may affect the realization of forward-looking statements, including the forward-looking statements in this press release, is set forth in SIGA's filings with the Securities and Exchange Commission, including SIGA's Annual Report on Form 10-K for the year ended December 31, 2019, and in other documents that SIGA has filed with the SEC. SIGA urges investors and security holders to read those documents free of charge at the SEC's web site at http://www.sec.gov. Interested parties may also obtain those documents free of charge from SIGA. Forward-looking statements are current only as of the date on which such statements were made, and except for our ongoing obligations under the United States of America federal securities laws, we undertake no obligation to update publicly any forward-looking statements whether as a result of new information, future events, or otherwise.

The information contained in this press release does not necessarily reflect the position or the policy of the government and no official endorsement should be inferred.

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[1] http://www.mayoclinic.org/diseases-conditions/smallpox/basics/definition/con-20022769

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