SIGA Awarded Department of Defense Contract to Develop Expanded Indication for TPOXX® as Post-Exposure Prophylactic for Smallpox

July 8, 2019

NEW YORK, July 08, 2019 (GLOBE NEWSWIRE) -- SIGA Technologies, Inc. (SIGA) (NASDAQ: SIGA), a commercial-stage pharmaceutical company focused on the health security market, today announced that it has been awarded a multi-year contract from the United States Department of Defense (DoD) to support work necessary to gain a potential label expansion for TPOXX® (tecovirimat) that would include Post-Exposure Prophylaxis (PEP) of smallpox. The contract is valued at up to $19.5 million, with an initial award of $12.4 million. The initial funding will support several activities, including manufacturing material for clinical trials, initial preparation for a human clinical safety study, and assembling regulatory filings that SIGA has designed with input from the U.S. Food and Drug Administration (FDA) to evaluate the use of TPOXX for PEP. As previously announced, SIGA is already working with the U.S. Army Medical Research Institute of Infectious Disease on animal studies to evaluate the efficacy of TPOXX as a potential PEP therapy for smallpox.

The use of TPOXX for PEP could provide significant potential benefit in the event of a smallpox outbreak. While vaccines would play an important role in containing the spread of smallpox, the vaccines 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 vaccine in combination with TPOXX could potentially be an important strategy for reducing morbidity and mortality in a smallpox outbreak.

"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 Phil Gomez, CEO of SIGA Technologies. "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. We have successfully collaborated with a number of U.S. government agencies in the development and approval of TPOXX for the treatment of smallpox, and are pleased to be working with DoD on these important studies."

On July 13, 2018, the FDA approved oral TPOXX for the treatment of smallpox to mitigate the impact of a potential outbreak or bioterror attack. TPOXX, a small-molecule antiviral treatment for smallpox, is the first therapy specifically approved for this indication, and was developed through funding and collaboration with Biomedical Advanced Research and Development Authority at the U.S. Department of Health and Human Services, as well as early stage development supported by the National Institutes of Health, U.S. Centers for Disease Control and Prevention, and DoD.

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 of which 2 million oral courses have been delivered to the Strategic National Stockpile under Project BioShield. The oral formulation of TPOXX was approved by the FDA for the treatment of smallpox on July 13, 2018. The full label is here: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/208627s000lbl.pdf. In September 2018, SIGA signed a new contract with Biomedical Advanced Research and Development Authority (BARDA) for additional procurement and development related to both oral and intravenous formulations of TPOXX. For more information about SIGA, please visit www.siga.com.

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 fiscal year ended December 31,

2018, 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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