SIGA Completes Clinical Studies for IV Formulation of TPOXX®, NDA to be Submitted in 2020

October 3, 2019

NEW YORK, Oct. 03, 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 reached concurrence with the US Food and Drug Administration (FDA) that no further clinical studies will be required for the IV formulation of TPOXX (tecovirimat), and SIGA anticipates filing the New Drug Application (NDA) for this formulation in 2020. Given that the efficacy of TPOXX was previously established in animal models used to support the development and approval of the oral formulation, the FDA will not require additional efficacy data to support the NDA for the IV formulation.

The IV formulation of TPOXX is an important option for the treatment of smallpox in those who may be too sick or unable to swallow the oral capsule formulation. The Biomedical Advanced Research and Development Authority (BARDA) emphasized the importance of this option in the 2018 contract award to SIGA, which specifies the delivery of 20,000 courses of the IV formulation of TPOXX and contains options for the purchase of up to an additional 192,000 courses of the formulation.

"We are pleased to reach this milestone with the FDA in the development of the IV formulation of TPOXX," said Phil Gomez, CEO of SIGA Technologies. "We will now focus on finalizing the commercial production capability for IV TPOXX and submitting the NDA in 2020." SIGA anticipates that the FDA will approve the IV formulation of TPOXX in 2021.

On July 13, 2018, the FDA approved the oral formulation of TPOXX (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 BARDA 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 Department of Defense.

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 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 on July 13, 2018. 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

Source: SIGA Technologies Inc.