SIGA Technologies Announces FDA Accepts NDA and Grants Priority Review for Oral TPOXX to Treat Smallpox

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- If approved, TPOXX would be the first treatment for smallpox -

NEW YORK, Feb. 07, 2018 (GLOBE NEWSWIRE) -- SIGA Technologies, Inc. (SIGA) (OTCMKTS:SIGA), a health security company specializing in the development and commercialization of solutions for serious unmet medical needs and biothreats, today announced that the U.S. Food and Drug Administration (FDA) has accepted the company's New Drug Application (NDA) for its oral formulation of TPOXX® (tecovirimat). TPOXX is a novel small molecule antiviral therapy for smallpox infection. SIGA requested priority review of its TPOXX NDA at the time the filing was submitted because smallpox infection is a deadly disease for which no cure or treatment currently exists. The FDA advised that it has granted priority review to the application, meaning that the agency will target completing its review in six rather than ten months. In light of the NDA submission on December 8, 2017, the FDA has notified SIGA that the agency's target final action date is August 8, 2018.

The U.S. government's Biomedical Advanced Research and Development Authority (BARDA) funded the advanced development of oral TPOXX in partnership with SIGA. Additionally, under Project Bioshield, BARDA has purchased two million courses of oral TPOXX and such courses have been delivered to the Strategic National Stockpile (SNS).

"We are very pleased that the FDA has accepted our NDA for oral TPOXX. This is an important milestone in the regulatory review of our pending application. Based on a comprehensive submission that includes extensive positive efficacy data in animal studies and human clinical safety data without any drug-related Serious Adverse Events, we look forward to a favorable, expedited review of the application," said Dr. Phil Gomez, Chief Executive Officer of SIGA Technologies, Inc. "A positive FDA review would represent an important milestone not only for SIGA, but for our federal government partners that have provided invaluable support throughout development of the product. Our public-private collaboration serves as an important example of how such partnerships can advance novel drugs for unmet medical needs. Eventual approval of this product would be an important step in advancing health security against the serious threat of a potential smallpox-based bioterror attack."

TPOXX (tecovirimat) was developed under the FDA "Animal Rule," in which efficacy endpoints are determined in animal studies, and human clinical studies are conducted to determine safety and confirm dosing. The TPOXX NDA comprised extensive positive efficacy data in animal studies and human clinical safety data demonstrating that there have been no drug-related Serious Adverse Events during the development of oral TPOXX.

ABOUT SIGA TECHNOLOGIES, INC. and TPOXX®

SIGA Technologies, Inc. is a health security company specializing in the development and commercialization of solutions for serious unmet medical needs and biothreats. The company's lead product is TPOXX®, also known as tecovirimat and ST-246®, an orally administered and IV formulation antiviral drug that targets orthopoxvirus infections. While TPOXX™ is not yet approved as safe and effective by the U.S. Food & Drug Administration, it is a novel small-molecule drug of which 2 million courses have been delivered to the Strategic National Stockpile under Project BioShield. 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. No cure or treatment for smallpox exists. A vaccine can prevent smallpox, but the risk of the 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, including statements relating to the submission and approval of TPOXX® by the FDA. 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, 2016, 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.

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

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