



SIGA Technologies Announces FDA Submission of its New Drug Application for oral TPOXX (tecovirimat) to Treat Smallpox

December 11, 2017

– Company requests Priority Review of TPOXX NDA –

– If approved, would be the first treatment for deadly smallpox –

NEW YORK, Dec. 11, 2017 (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 the submission of its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for the oral formulation of TPOXX® (tecovirimat). TPOXX was developed to treat smallpox, as well as other orthopoxvirus infections. No cure or treatment for smallpox exists. The advanced development of TPOXX has been funded by the U.S. government's Biomedical Advanced Research and Development Authority (BARDA). Pursuant to a contract with BARDA, SIGA has successfully delivered two million courses of TPOXX to the Strategic National Stockpile.

A photo accompanying this announcement is available at <http://www.globenewswire.com/NewsRoom/AttachmentNg/27db571c-1ea6-4a3f-aa55-3bab07f1f76f>

"We are very pleased to have achieved this important milestone in the development of TPOXX. If approved, TPOXX would be the first ever treatment for smallpox," said Dr. Phil Gomez, Chief Executive Officer of SIGA Technologies, Inc. "Based on extensive positive efficacy data in animal studies and human clinical safety data without any drug-related Serious Adverse Events, we believe the NDA for oral TPOXX is well positioned for favorable, expedited review by the FDA. This is an important milestone not only for SIGA, but an important example of how public-private partnerships can advance novel drugs for unmet medical needs towards FDA licensure. This NDA filing is also an important step in advancing health security against the growing threat of a potential smallpox-based bioterror attack."

Based on regulatory review requirements, in light of SIGA's NDA submission on Friday December 8, 2017, the Company expects in February 2018 to receive notification from the FDA that the filing was accepted for review, confirmation of priority review status, and notification of its final action date. Since TPOXX is designed to treat a serious medical condition for which there is no approved therapy, SIGA has requested expedited review of its application.

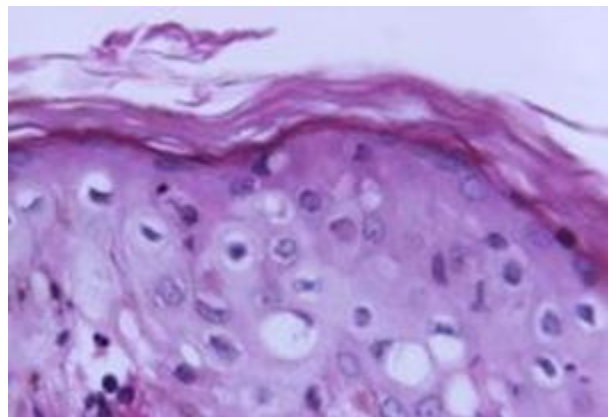
TPOXX (tecovirimat) was developed under the FDA "Animal Rule," in which efficacy endpoints are determined in animal studies, and human clinical studies are conducted to determine safety and confirm dosing. There have been no drug-related Serious Adverse Events (SAEs) during the development of oral TPOXX.

ABOUT SIGA TECHNOLOGIES, INC. and TPOXX®

SIGA Technologies, Inc. is a 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 Smallpox¹

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.



Source: Communicable Disease Control and Prevention, San Francisco Dept. of Public Health

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

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 U.S. 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. SIGA's actual results could differ materially from those anticipated by such forward-looking statements due to a number of factors, some of which are beyond SIGA's control, including, but not limited to, (i) the risk that potential products that appear promising to SIGA or its collaborators cannot be shown to be efficacious or safe in subsequent pre-clinical or clinical trials, (ii) the risk that SIGA or its collaborators will not obtain appropriate or necessary governmental approvals to market these or other potential products, (iii) the risk that SIGA may not be able to obtain anticipated funding for its development projects or other needed funding, including from anticipated governmental contracts and grants, (iv) the risk that SIGA may not complete performance under the Biomedical Advanced Research Development Authority (BARDA) Contract on schedule or in accordance with contractual terms, (v) the risk that SIGA may not be able to secure or enforce sufficient legal rights in its products, including intellectual property protection, (vi) the risk that any challenge to SIGA's patent and other property rights, if adversely determined, could affect SIGA's business and, even if determined favorably, could be costly, (vii) the risk that regulatory requirements applicable to SIGA's products may result in the need for further or additional testing or documentation that will delay or prevent seeking or obtaining needed approvals to market these products, (viii) the risk that one or more protests could be filed and upheld in whole or in part or other governmental action taken, in either case leading to a delay of performance under the BARDA Contract or other governmental contracts, (ix) the risk that the BARDA Contract is modified or canceled at the request or requirement of the U.S. government, (x) the risk that the volatile and competitive nature of the biotechnology industry may hamper SIGA's efforts to develop or market its products, (xi) the risk that the changes in domestic and foreign economic and market conditions may affect SIGA's ability to advance its research or may affect its products adversely, (xii) the effect of federal, state, and foreign regulation, including drug regulation and international trade regulation, on SIGA's businesses, (xviii) the risk that our internal controls will not be effective in detecting or preventing a misstatement in our financial statements, (xiv) the risk that some amounts received and recorded as deferred revenue may someday be determined to have been more properly characterized as revenue when received, and (xv) the risk that some amounts received and recorded as deferred revenue ultimately may not be recognized as revenue. 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.

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Source: SIGA Technologies, Inc.