



## **SIGA Announces Canadian Release of the Advanced Contract Award Notice to Support Regulatory Filing for Oral TPOXX®**

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NEW YORK, Nov. 18, 2019 (GLOBE NEWSWIRE) -- SIGA Technologies, Inc. (SIGA) (NASDAQ: SIGA), a commercial-stage pharmaceutical company focused on the health security market, today announced that the Canadian Department of National Defence (CDND) has issued an advanced contract award notice (ACAN), indicating that it intends to award a contract to fund regulatory filing with Health Canada for approval of oral TPOXX®. The ACAN is required to remain open for approximately 15 days, during which time a potential alternative supplier who meets the ACAN requirements for a smallpox anti-viral therapy that has been approved by national regulatory authority may submit a competing Statement of Capabilities. SIGA is the only company currently able to fulfill this requirement.

"The ACAN represents an important first step by the Canadian military, to ultimately provide TPOXX as a medical countermeasure for smallpox. In the past, Canada has pursued initial procurement of medical countermeasures prior to full regulatory approval and pursuant to emergency use authorization as a strategy for protecting its citizens from potential bio-threats, with additional, larger procurements typically following such approval," said Dr. Phil Gomez, CEO of SIGA Technologies. "As a result, this ACAN is an important first step in Canada's efforts to enhance its smallpox preparedness with an anti-viral product. We are pleased that the CDND has identified TPOXX as the only smallpox treatment qualified to fulfill its requirements. We look forward to working with the appropriate Canadian authorities on the next steps in preparation of a regulatory filing for oral TPOXX, which is initially targeted for 2020, and ultimate delivery of this important smallpox antiviral therapy to help protect the people of Canada."

The ACAN notice can be found at: <https://buyandsell.gc.ca/procurement-data/tender-notice/PW-19-00896089>.

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 the 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 Department of Defense. The US currently maintains a stockpile of 1.7 million courses of TPOXX.

In June, 2019, SIGA entered into an international promotion agreement with Meridian Medical Technologies, Inc. ("Meridian", a Pfizer Company). Under the agreement, Meridian will promote the sale of oral TPOXX for the treatment of smallpox in all international markets, except the United States and South Korea. SIGA will continue to own all rights to the product and its related intellectual property.

### **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 oral 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](http://www.siga.com).

### **ABOUT MERIDIAN MEDICAL TECHNOLOGIES, INC.**

Meridian Medical Technologies, Inc., a Pfizer company, has been putting emergency care treatment options into the hands of military and civilian defenders for more than 50 years. Meridian is committed to help defend against critical, time-sensitive, life-or-death situations by providing medical countermeasures to the United States Department of Defense, Emergency Medical Services, Homeland Security, and more than 30 nations around the world.

Meridian holds a federal SAFETY Act designation and certification from the Department of Homeland Security for its portfolio of auto-injectors. The SAFETY Act is intended to provide critical incentives for the development and deployment of anti-terrorism technologies by providing liability protections for sellers of qualified anti-terrorism technologies.

### **About Smallpox<sup>1</sup>**

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



Source: SIGA Technologies Inc.