



SIGA Technologies Awarded BARDA Contract for TPOXX®

September 10, 2018

- Contract Valued at Up to \$629 Million –

- Contract Includes Delivery of Oral and Intravenous (IV) Formulations of TPOXX; Development of IV TPOXX; Post-marketing Activities –

NEW YORK, Sept. 10, 2018 (GLOBE NEWSWIRE) -- SIGA Technologies, Inc. (SIGA) (NASDAQ: SIGA), a commercial-stage pharmaceutical company focused on the health security market, today announced that it has signed a multi-year contract with the Biomedical Advanced Research and Development Authority (BARDA), a division of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response, for the delivery of oral and intravenous (IV) formulations of TPOXX® to the Strategic National Stockpile. The contract also covers advanced development of the IV formulation and post-marketing activities for the oral formulation of TPOXX. The contract (HHSO100201800019C) is valued at up to \$629 million, and consists of a five-year base period of performance and a total contract period of performance (base period plus option exercises) of up to ten years (if necessary). The contract contains base period activities and a series of options, and is designed to maintain a stockpile of 1.7 million courses of antiviral treatment for smallpox.

On July 13, 2018, the U.S. Food and Drug Administration (FDA) approved oral TPOXX® (tecovirimat) for the treatment of smallpox to mitigate the impact of a potential outbreak. TPOXX, a small-molecule antiviral treatment for smallpox, is the first therapy specifically approved for this indication.

"This contract builds on the strong foundation of the SIGA and BARDA partnership and we look forward to working closely with BARDA to ensure the current U.S. stockpile is adequately maintained," said Phil Gomez, CEO of SIGA Technologies. "The contract provides excellent value to the U.S. Government for the mitigation of the risks of a smallpox outbreak, outlines a roadmap for sustaining the current stockpile, and adds the IV formulation of TPOXX as an available alternative treatment option."

Under contract HHSO100201800019C, base period activities are valued at approximately \$52 million and include:

- Development activities for the IV formulation of TPOXX (IV TPOXX).
- Delivery to the Strategic National Stockpile (SNS) of a limited number of courses (approximately 35,700 courses) of the oral formulation of TPOXX (oral TPOXX) for an approximate value of \$11 million; such courses being readily-available for delivery or will be manufactured using currently-held active pharmaceutical ingredient.
- Delivery of bulk drug substance to be used for the manufacture of IV TPOXX and the use of such bulk drug substance to manufacture 20,000 courses of final drug product of IV TPOXX, with such activities having a total value of \$8 million for 7-day (14-vial) courses; additionally, SIGA will be paid for the storage, if applicable, and delivery of final drug product of IV TPOXX.

With options valued at approximately \$577 million in total (if all options are fully exercised), contract HHSO100201800019C is primarily comprised of options that are exercisable at the sole discretion of BARDA.

Options within the contract include:

- Series of options to procure up to approximately 1,452,300 courses in total of oral TPOXX (exclusive of the courses to be purchased for base period activities), with such options having a total value of up to approximately \$450 million.
- Series of options to procure up to 192,000 courses in total (exclusive of the courses to be purchased for base period activities) of final drug product of IV TPOXX, with such options having a cumulative total value of up to approximately \$77 million for the combination of bulk drug substance and final drug product manufacturing; or alternatively, to procure up to 192,000 equivalent courses in total (exclusive of the equivalent courses to be purchased for base period activities) of bulk drug substance that could be used in the future for the manufacture of final drug product of IV TPOXX, with such alternative having a value of up to approximately \$31 million.
- Series of options for vendor-managed storage of either bulk drug substance that would be used in the manufacture of the IV TPOXX or final drug product of IV TPOXX (total option value of approximately \$6 million).
- Separate options to cumulatively provide up to approximately \$44 million of funding for post-marketing activities for oral TPOXX and IV TPOXX.

This BARDA contract (HHSO100201800019C) becomes the third active contract between the Company and BARDA. Under contract

HHSO100201100001C, BARDA funded late-stage development of oral TPOXX for the treatment of smallpox, which culminated in the U.S. Food and Drug Administration (FDA) approval on July 13, 2018, and the acquisition of 2 million courses of oral TPOXX which the Company has delivered. Under contract HHSO100201100023C, the Company receives funding from BARDA for the development of the IV formulation of TPOXX to provide a treatment option for patients who are too sick or unable to swallow oral capsules. It is anticipated that patients taking the IV formulation would eventually "step-down" to the oral formulation, once they are able to swallow capsules. To accommodate this dosing regimen, contract HHSO100201800019C includes an initial order and options for the purchase of up to 212,000 treatment courses (in total) of IV therapy, and each treatment course is expected to cover seven (7) days (14 vials) of treatment. Oral TPOXX approval and procurement is based upon 14 total days of therapy.

This contract will be funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No HHSO100201800019C.

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 Food and Drug Administration (FDA) for the treatment of smallpox on July 13, 2018. 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.

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 future exercise of options by BARDA for procurement of TPOXX®. 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, 2017, 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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¹ <http://www.mayoclinic.org/diseases-conditions/smallpox/basics/definition/con-20022769>



Source: SIGA Technologies Inc.