



SIGA Announces New Drug Application Filing with FDA for Intravenous Formulation of TPOXX

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- Important for Patients Who Cannot Swallow Oral Capsules -

NEW YORK, May 04, 2021 (GLOBE NEWSWIRE) -- SIGA Technologies, Inc. (SIGA) (NASDAQ: SIGA), a commercial-stage pharmaceutical company focused on the health security market, today announced that it has filed a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for the intravenous formulation (IV) of TPOXX®. The proposed indication, for the treatment of human smallpox disease in adults and pediatric patients weighing 13 kg or more, is the same as what was approved by the FDA in July 2018 for the oral formulation of TPOXX. The IV formulation will enable those patients who are too sick or unable to swallow capsules to be treated with TPOXX, thereby adding a significant new patient population.

"This is our first application for regulatory approval of IV TPOXX, and we are pleased to be achieving this milestone to support maximum access to the product among a broader patient population in case of an emergency or outbreak," said Dr. Phil Gomez, CEO of SIGA. "The ongoing COVID-19 pandemic has highlighted the importance for governments to build robust stockpiles of products that will support effective responses to infectious disease outbreaks, including smallpox, which remains a significant bioterror threat and could be an even more devastating disease than COVID-19."

"SIGA developed IV TPOXX in partnership with the U.S. government, and the combined expertise has helped generate a robust set of data supporting the NDA for the IV product," said Dr. Dennis Hruby, CSO of SIGA. "As a result of the extensive effort that went into our initial filing with the FDA, we were not required to complete any additional pre-clinical or clinical work for our IV application. We look forward to working with the FDA so that the expanded patient population can benefit from treatment with IV TPOXX."

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 (BARDA), part of the office of the Assistant Secretary for Preparedness and Response 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.

On September 10, 2018, the Company entered into a contract with BARDA pursuant to which SIGA agreed to manufacture and deliver to the U.S. government, or store as vendor-managed inventory, the IV formulation of TPOXX. Additionally, the 2018 BARDA contract includes funding for advanced development of IV TPOXX, and post-marketing activities for IV TPOXX, among other activities.

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 supply of TPOXX under Project BioShield. The oral formulation of TPOXX was approved by the FDA for the treatment of smallpox in 2018. The full label is available by [clicking here](#). In September 2018, SIGA signed a \$51.6M contract with \$577M in options with 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 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. 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, 2020, 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.