SIGA Announces Marketing Authorization Filing for oral tecovirimat with the European Medicines Agency for Multiple Indications

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- Broader Indication to Include Smallpox, Monkeypox, Cowpox, and Vaccinia Complications -

NEW YORK, July 30, 2020 (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 Marketing Authorisation Application (MAA) with the European Medicines Agency (EMA) for oral tecovirimat, the same formulation that was approved by the U.S. Food and Drug Administration (FDA) in July 2018 under the name TPOXX®. The MAA was filed under the centralized application process, which, upon approval, and will enable sales and marketing of oral tecovirimat in all EU member states, as well as Norway, Iceland, and Liechtenstein. SIGA has filed its application for oral tecovirimat seeking a broader label indication covering the treatment of smallpox, monkeypox, cowpox, and complications from Vaccinia infection. SIGA is targeting approval for the second half of 2021.

"This is our first ex-US application for oral tecovirimat regulatory approval, and we are pleased to be working with the EMA to ensure maximum access to the product throughout Europe," said Dr. Phil Gomez, CEO of SIGA. "The ongoing COVID-19 pandemic has highlighted the importance for governments around the world to build robust stockpiles that will support effective responses to infectious disease outbreaks, including smallpox, which is a significant bioterror threat and would be an even more devastating disease than COVID-19. This is also an important step in our international strategy for tecovirimat for maximizing access to the European market."

"SIGA developed oral tecovirimat in partnership with the U.S. Government, and the combined expertise generated a robust set of data supporting the efficacy and safety of the 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 EMA application. We look forward to working with the EMA on the broader indication included in the MAA, as there are active cases of monkeypox, cowpox, and vaccinia complications in patients that could potentially benefit from treatment with tecovirimat. We are committed to ensuring broad access to the product for patients throughout Europe."

On July 13, 2018, the FDA approved oral TPOXX (tecovirimat) 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. Under the agreement, Meridian will promote the sale of oral tecovirimat 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. On June 1, 2020, SIGA announced its first international sale with 2,500 courses delivered to the Canadian Department of National Defence.

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 the Biomedical Advanced Research and Development Authority (BARDA), part of the office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services, 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 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[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. 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, 2019, 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.