



SIGA Technologies Receives Approval from the European Medicines Agency for Tecovirimat

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

NEW YORK, Jan. 10, 2022 (GLOBE NEWSWIRE) -- SIGA Technologies, Inc. (SIGA) (NASDAQ: SIGA), a commercial-stage pharmaceutical company focused on the health security market, today announced that the European Medicines Agency (EMA) approved SIGA's Marketing Authorisation Application (MAA) for oral tecovirimat, the same formulation that was approved by the U.S. Food and Drug Administration (FDA) in July 2018 under the brand name TPOXX®. The EMA approval includes labeling for oral tecovirimat indicating its use for the treatment of smallpox, monkeypox, cowpox, and vaccinia complications following vaccination against smallpox. The MAA was filed under the centralized application process, which, upon approval, enables sales, including procurement for stockpiling, of oral tecovirimat in all European Union (EU) member states, as well as Norway, Iceland, and Liechtenstein.

"We are grateful to the EMA for their hard work leading to approval of tecovirimat, which will enable maximum access to the product throughout Europe for a broader range of uses," said Dr. Phil Gomez, CEO of SIGA. "The ongoing COVID-19 pandemic has underscored the importance of preparedness, a component of which is governments around the world building robust stockpiles that will support effective responses to infectious disease outbreaks such as smallpox, a significant bioterror threat that could be even more devastating than COVID-19. EMA approval is an important step in our international strategy for tecovirimat to be available in the European market and beyond."

In June 2019, SIGA entered into an international promotion agreement with Meridian Medical Technologies, Inc. ("Meridian"). Under the agreement, Meridian will promote the sale of oral tecovirimat for the treatment of smallpox in all international markets outside of the United States. SIGA will continue to own all rights to the product and its related intellectual property. "We are excited about the EMA's approval of tecovirimat for use in the EU, as it reinforces the commitment to the health security market and underscores the importance for global preparedness," said Tom Handel, Chief Commercial Officer. "The business alliance SIGA and Meridian share showcases the collective goal of not only raising awareness around smallpox as a biothreat, deliberate or accidental, but also emphasizes the critical aspects of making a treatment available for both military and civil defense."

SIGA announced in late 2021 that TPOXX was also approved by Health Canada.

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, and was [approved by the EMA](#) for the treatment of smallpox, monkeypox, cowpox, and vaccinia complications following vaccination against smallpox in January 2022. In September 2018, SIGA signed a contract 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., an Altaris Capital Partners company, has been putting emergency care treatment options into the hands of military and civilian defenders for more than 60 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.

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.