



## **European Medicines Agency Committee for Medicinal Products for Human Use (CHMP) Recommends Approval of Tecovirimat**

November 16, 2021

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

NEW YORK, Nov. 16, 2021 (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 Committee for Medicinal Products for Human Use (CHMP) published their summary opinion in support of approval of SIGA's Marketing Authorisation Application (MAA) for oral tecovirimat. Oral tecovirimat is the same formulation that was approved by the U.S. Food and Drug Administration in July 2018 under the brand name TPOXX®. The recommendation from the CHMP, which plays a vital role in conducting the scientific assessment of MAAs, included support for broader labeling for oral tecovirimat indicating its use for the treatment of smallpox, monkeypox, cowpox, and vaccinia complications. The MAA was filed under the centralized application process, which, upon approval, will enable sales and marketing of oral tecovirimat in all EU member states, as well as Norway, Iceland, and Liechtenstein. SIGA is targeting EMA approval for the first quarter of 2022.

"We are grateful to the CHMP for their hard work and support of tecovirimat for approval with the EMA, which would enable maximum access to the product throughout Europe," said Dr. Dennis Hruby, CSO 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 allow 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."

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 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.

SIGA also has an application pending for approval of oral tecovirimat with Health Canada. In 2020 and 2021, SIGA announced international sales with the Canadian Department of National Defence and Public Health Agency of Canada (PHAC).

### **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 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](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.

On November 1, 2021, Pfizer entered into an agreement with Altaris Capital Partners, LLC ("Altaris"), a health care investment firm based in New York, for Altaris to purchase Meridian. The transaction is expected to close in the coming months, subject to customary closing conditions including the receipt of regulatory approvals.

### **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, 2021, 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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<sup>1</sup> <http://www.mayoclinic.org/diseases-conditions/smallpox/basics/definition/con-20022769>



Source: SIGA Technologies Inc.