SIGA Announces Start of TPOXX® Post-Exposure Prophylactic ("PEP") Clinical Trials

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NEW YORK, March 02, 2022 (GLOBE NEWSWIRE) -- SIGA Technologies, Inc. (SIGA) (NASDAQ: SIGA), a commercial-stage pharmaceutical company focused on the health security market, today announced that it has initiated the clinical program to support a U.S. Food and Drug Administration (FDA) label expansion for Post-Exposure Prophylaxis ("PEP") for oral TPOXX®, approved in July 2018 for the treatment of smallpox. The first study is a comparison of the enrolled participants' immune response with the Jynneos smallpox vaccines compared with the immune response with Jynneos while on TPOXX treatment. The study is designed to determine if TPOXX interferes with the development of an effective immune response to the vaccine. A second clinical study, also expected to commence in 2022, will look at developing an expanded safety dataset to support 28 day dosing of TPOXX for the post-exposure prophylaxis indication compared with the currently approved 14 days for treatment of smallpox indication.

"The use of TPOXX for post-exposure prophylaxis has always been an important opportunity for TPOXX use in an outbreak of smallpox," said Dr. Phil Gomez, CEO of SIGA. "This was highlighted by the US Government during our initial 2011 procurement, and discussed extensively at our FDA Advisory committee meeting in 2018 where TPOXX received a unanimous vote to recommend approval for treatment of smallpox. The COVID-19 pandemic has also shown vaccine hesitancy is a real issue for pandemic response, and the balance of vaccines and anti-viral drugs in stockpiles must be reevaluated in light of current experience."

SIGA has been collaborating with the U.S. Department of Defense's Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) to develop the PEP indication, and this work is supported by an approximately $26 million R&D contract. "There have been long-standing concerns that smallpox could be used as a bioweapon," said Col. Ryan Eckmeier, the Joint Project Manager for CBRN Medical. "This PEP indication could help protect a wider range of warfighters against that threat."

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. In December 2021, oral TPOXX was approved for the same indication by Health Canada. Tecovirimat (TPOXX) was approved by the European Medicines Agency (EMA) in January 2022 with a broader label that covers the treatment of smallpox, monkeypox, cowpox, and complications from vaccination for smallpox.

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. Oral tecovirimat received approval from the European Medicines Agency (EMA) in 2022. 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 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, under contract 75A50118C00019, 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 Smallpox

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.

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.

Disclaimer: Included references to commercial products does not constitute endorsement by the U.S. Department of Defense or the JPEO-CBRND.

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