SIGA Provides Update on Progress in Clinical Trials to Assess Use of TPOXX ® (tecovirimat) for Treatment of Monkeypox

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- *Trials are currently underway in the United States, United Kingdom and Democratic Republic of Congo*
- *Pending positive results from clinical trials, SIGA plans to file with U.S. regulators for regulatory review of a TPOXX expanded indication for treatment of monkeypox*

NEW YORK, Oct. 12, 2022 (GLOBE NEWSWIRE) -- SIGA Technologies, Inc. (SIGA) (NASDAQ: SIGA), a commercial-stage pharmaceutical company focused on the health security market, today provided an update on the status of multiple clinical trials now underway to assess the safety and efficacy of TPOXX to treat monkeypox.

In recent weeks, randomized, placebo-controlled clinical trials were initiated in three countries including the United States, United Kingdom and Democratic Republic of Congo (DRC) to further assess the safety and efficacy of TPOXX in participants with monkeypox. These randomized clinical trials are now enrolling patients to collect data on the potential benefits of using TPOXX as an antiviral treatment for active monkeypox disease.

About the clinical trials:

- *Study of Tecovirimat for Human Monkeypox Virus (STOMP; A5418)* is a U.S.-based clinical trial sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). The NIAID-funded AIDS Clinical Trials Group (ACTG) is leading the study, which may later expand to international sites. Study investigators aim to enroll more than 500 participants, including children and those who are pregnant or breastfeeding, from clinical research sites. The trial will also include an open label arm that will include children, pregnant/breastfeeding individuals and those who are immunocompromised or have severe monkeypox disease.
- *PLATINUM* is a U.K.-based clinical trial commissioned and funded by the National Institute for Health Care and Research (NIHR). The trial is being led by researchers at Oxford University and aims to recruit at least 500 participants, including children weighing ≥13 kg, across the U.K.
- *PALM 007* is a DRC-based clinical trial sponsored by NIAID and Institute National de Recherche Biomédicale (INRB). Study investigators aim to enroll more than 450 participants, including children weighing ≥3 kg and those who are pregnant or breastfeeding, at clinical sites in the DRC.

“We are grateful for the outstanding efforts of our collaborators and partners across the globe to quickly launch placebo-controlled studies to evaluate TPOXX,” said Phillip Gomez, CEO of SIGA. “As the global monkeypox outbreak continues to evolve, these studies can provide new levels of data and further confirm findings related to safety and efficacy that can support regulatory review and potential approval of TPOXX for the treatment of monkeypox in the United States and other countries.”

On July 13, 2018, the US Food and Drug Administration (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 and the Medicines and Healthcare products Regulatory Agency (MHRA) in June 2022 with a broader label that covers the treatment of smallpox, monkeypox, cowpox, and complications from vaccination for smallpox.

In addition to providing support for clinical trials, SIGA continues to respond to TPOXX procurement order requests from countries around the world. In a separate press release in September, SIGA disclosed that the Company had received, as of mid September, approximately $76 million of international orders for oral TPOXX from twelve international customers.

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 U.S. 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 the IV formulation was approved for the same indication in 2022. The full label is available by clicking here. Oral tecovirimat received approval from the European Medicines Agency (EMA) and the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom in 2022. The EMA

and UK approvals include 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, for additional procurement and development related to both oral and intravenous formulations of TPOXX. This project has been funded in whole or in part with federal funds from the Administration for Strategic Preparedness and Response, Biomedical Advanced Research and Development Authority, under contract number HHSO100201800019C. 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.

About Monkeypox

Monkeypox is a disease caused by infection with the monkeypox virus, which is in the same family of viruses as smallpox. Monkeypox symptoms are similar to smallpox, but not as severe and with historical mortality of less than 1% to 10% depending on region and clade. The first human case of monkeypox was recorded in 1970. Since then, monkeypox has been reported in several central and western African countries, with case numbers greatly increasing in recent years because the virus is endemic in those countries. Prior to the ongoing 2022 outbreak, nearly all monkeypox cases in people outside of Africa were linked to international travel to countries where the disease commonly occurs, or through imported animals, including two cases in the United States in 2021. These cases are currently occurring on multiple continents. On July 23, 2022, the World Health Organization (WHO) declared the monkeypox outbreak a public health emergency of international concern. On August 4, 2022, the U.S. government declared the monkeypox outbreak as a public health emergency.

FORWARD-LOOKING STATEMENTS

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including statements relating to the progress of SIGA’s development programs and timelines for bringing products to market, delivering products to the Strategic Stockpile, the enforceability of our procurement contracts, such as the 19C BARDA Contract (the "BARDA Contracts"), with BARDA, the impact of the COVID pandemic and responding to the global outbreak of monkeypox. The words or phrases “can be,” “expects,” “may affect,” “may depend,” “believes,” “estimate,” “project” and similar words and phrases are intended to identify such forward-looking statements. 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. SIGA’s actual results could differ materially from those anticipated by such forward-looking statements due to a number of factors, some of which are beyond SIGA’s control, including, but not limited to, (i) the risk that BARDA elects, in its sole discretion as permitted under the BARDA Contracts, not to exercise all, or any, of the remaining unexercised options under those contracts, (ii) the risk that SIGA may not complete performance under the BARDA Contracts on schedule or in accordance with contractual terms, (iii) the risk that the BARDA Contracts are modified or canceled at the request or requirement of the U.S. Government, (iv) the risk that the nascent international biodefense market does not develop to a degree that allows SIGA to successfully market TPOXX® internationally, (v) the risk that potential products, including potential alternative uses or formulations of TPOXX® that appear promising to SIGA or its collaborators, cannot be shown to be efficacious or safe in subsequent pre-clinical or clinical trials, (vi) the risk that SIGA or its collaborators will not obtain appropriate or necessary governmental approvals to market these or other potential products or uses, (vii) the risk that SIGA may not be able to secure or enforce sufficient legal rights in its products, including intellectual property protection, (viii) the risk that any challenge to SIGA’s patent and other property rights, if adversely determined, could affect SIGA’s business and, even if determined favorably, could be costly, (ix) the risk that regulatory requirements applicable to SIGA’s products may result in the need for further or additional testing or documentation that will delay or prevent SIGA from seeking or obtaining needed approvals to market these products, (x) the risk that the volatile and competitive nature of the biotechnology industry may hamper SIGA’s efforts to develop or market its products, (xi) the risk that changes in domestic or foreign economic and market conditions may affect SIGA’s ability to advance its research or may affect its products adversely, (xii) the effect of federal, state, and foreign regulation, including drug regulation and international trade regulation, on SIGA’s businesses, (xiii) the risk of disruptions to SIGA’s supply chain for the manufacture of TPOXX ®, causing delays in SIGA’s research and development activities, causing delays or the re-allocation of funding in connection with SIGA’s government contracts, or diverting the attention of government staff overseeing SIGA’s government contracts, (xiv) the risk that the U.S. or foreign governments' responses (including inaction) to national or global economic conditions or infectious diseases, such as COVID-19, are ineffective and may adversely affect SIGA’s business, and (xv) risks associated with responding to the current monkeypox outbreak, as well as the risks and uncertainties included in Item 1A “Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2021 and SIGA's subsequent filings with the Securities and Exchange Commission. SIGA urges investors and security holders to read those documents free of charge at the SEC's website at http://www.sec.gov. All such forward-looking statements are current only as of the date on which such statements were made. SIGA does not undertake any obligation to update publicly any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

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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