SIGA Receives Approval from the FDA for Intravenous (IV) Formulation of TPOXX® (tecovirimat)

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- FDA approval provides an important option for those unable to take oral formulation of TPOXX -

NEW YORK, May 19, 2022 (GLOBE NEWSWIRE) -- SIGA Technologies, Inc. (SIGA) (NASDAQ: SIGA), a commercial-stage pharmaceutical company focused on the health security market, today announced that the U.S. Food and Drug Administration (FDA) approved the intravenous (IV) formulation of TPOXX for the treatment of smallpox. The IV formulation is an important option for those who are unable to swallow the oral capsules of TPOXX.

"We are grateful to the FDA for their work leading to approval of IV TPOXX, which will provide access to a broader patient population," said Dr. Dennis Hruby, CSO of SIGA. "We are also appreciative to our colleagues at BARDA who have been working with us for many years to include oral and IV TPOXX in U.S. preparedness efforts and look forward to continuing to work with them on our liquid pediatric formulation."

The oral formulation of TPOXX (tecovirimat) is approved in the US, Canada and Europe for the treatment of smallpox. The European approval also includes the treatment of monkeypox, cowpox, and complications from immunization with vaccinia. The IV formulation of TPOXX was cited in the recent U.S. president's budget request as being used to treat a patient in the U.S. with monkeypox.

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. Funding and technical support for this work is provided by the Biomedical Advanced Research and Development Authority (BARDA), under the Assistant Secretary for Preparedness and Response (ASPR), within the U.S. Department of Health and Human Services (HHS), under ongoing USG Contract No. 75A50118C00019 (19C). For more information about BARDA, refer to https://www.medicalcountermeasures.gov/. 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.

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 "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, as well as the impact of COVID-19 on SIGA's business. Forward-looking statements may be identified by words or phrases such as "believes," "estimates," "expects," "may," "will," "would," "can," "could," and similar words and phrases. Such forward-looking statements are based on current expectations and assumptions and 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 the U.S. Biomedical Advanced Research and Development Authority ("BARDA") elects, in its sole discretion as permitted under the BARDA Contracts (as defined below), not to exercise all, or any, of the remaining unexercised options under those contracts, (ii) the risk that SIGA may not complete performance under its contracts with BARDA (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 that the COVID-19 pandemic could impact SIGA's operations by disrupting 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 affect SIGA's business adversely, and (xv) other risk factors discussed in Item 1A. "Risk Factors" of SIGA's Annual Report on Form 10-K for the year ended December 31, 2021, and in SIGA's subsequent filings with the U.S. Securities and Exchange Commission. These documents are publicly available at the SEC's website at http://www.sec.gov and SIGA's website at https://investor.siga.com. Forward-looking statements are current only as of the date on which such statements were made, and except as may be otherwise required by law, 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

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