Pivotal Trial Data for SIGA Technologies' Oral TPOXX® Published in the New England Journal of Medicine

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- Results support the use of TPOXX to treat smallpox, a highly contagious and lethal virus that poses significant bioterror threat -

NEW YORK, July 05, 2018 (GLOBE NEWSWIRE) -- SIGA Technologies, Inc. (SIGA) (NASDAQ:SIGA), a commercial-stage pharmaceutical company focused on the health security market, which comprises countermeasures for biological, chemical, radiological and nuclear attacks as well as vaccines and therapies for emerging infectious diseases and health preparedness to address serious unmet medical needs, today announced the publication of data in the *New England Journal of Medicine* from its pivotal human safety and animal efficacy studies of its oral formulation of TPOXX® (tecovirimat). These results support the antiviral activity and favorable safety profile of TPOXX for the treatment of smallpox.

"Smallpox is both highly contagious and highly lethal and there is growing concern that smallpox could be used as a potential bioweapon," said Phil Gomez, PhD, SIGA's Chief Executive Officer. "A smallpox bioterror attack could be especially damaging because the majority of today's population is not immune to the virus, as routine vaccination ended in the 1970s. Rapid spread from person-to-person can occur through speaking, breathing or touching, and smallpox also can be transmitted by direct contact with infected fluids and contaminated objects. These factors underscore the need for an effective smallpox antiviral therapy, and we believe that TPOXX can address this need."

"The human safety and animal efficacy data reported in the *New England Journal of Medicine* are a large part of the TPOXX New Drug Application and support the use of this novel antiviral agent," said Dennis E. Hruby, PhD, Chief Scientific Officer at SIGA and senior author on the publication. "The absence of drug-related serious adverse events in the human safety trial coupled with a high survival rate in TPOXX-treated non-human primates receiving a lethal challenge dose of monkeypox virus establish a compelling risk-benefit profile for TPOXX in the treatment of smallpox."

TPOXX efficacy was investigated in lethal monkeypox/non-human primate (NHP) and rabbitpox/rabbit models in accordance with the Food and Drug Administration (FDA) "Animal Rule" interpreted for smallpox therapeutics by an expert advisory committee. A placebo-controlled human pharmacokinetic and safety study was performed in 449 adult volunteers. The minimum dose of TPOXX to achieve over 90% survival in the monkeypox/NHP model was 10 mg/kg for 14 days, while a dose of 40 mg/kg for 14 days was similarly efficacious in the rabbitpox/rabbit model. Although the effective dose per kg was higher in rabbits, exposure was lower suggesting that the NHP is the more conservative model for estimation of the required human drug exposure. Human dosing at 600 mg twice daily for 14 days was selected for testing, and provided exposures in excess of NHP exposures. No pattern of concerning adverse events was observed. Based on efficacy in two animal models and human PK and safety data, TPOXX is being advanced as a therapy for smallpox infection based on the FDA Animal Rule.

SIGA filed a New Drug Application (NDA) for oral TPOXX with the U.S. Food and Drug Administration (FDA) in December 2017 and, on May 1, 2018, TPOXX received a favorable outcome of the FDA's Antimicrobial Drugs Advisory Committee meeting. The panel, comprised of independent medical experts, voted unanimously, 17 to 0, that the benefits of TPOXX outweigh its risks. The FDA has previously announced that its target final action date for the oral TPOXX NDA is August 8, 2018.

The U.S. government's Biomedical Advanced Research and Development Authority (BARDA) funded the advanced development of oral TPOXX in partnership with SIGA. Additionally, under Project Bioshield, SIGA has delivered two million courses of oral TPOXX to the Strategic National Stockpile (SNS).

ABOUT SIGA TECHNOLOGIES, INC. and TPOXX®

SIGA Technologies, Inc. is 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. The company's lead product is TPOXX®, also known as tecovirimat, an orally administered and IV formulation antiviral drug that targets smallpox infections. While TPOXX® is not yet approved as safe and effective by the U.S. Food & Drug Administration, it is a novel small-molecule drug of which 2 million courses have been delivered to the Strategic National Stockpile (SNS) under Project BioShield. 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. No cure or treatment for smallpox exists. A vaccine can prevent smallpox, but the risk of the 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, including statements relating to the submission and approval of TPOXX® by the FDA. 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, 2017, 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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[1] http://www.mayoclinic.org/diseases-conditions/smallpox/basics/definition/con-20022769

Source: SIGA Technologies Inc.