SIGA Announces Collaboration with Oxford University to Support Expanded Access Protocol for Use of TPOXX® (Tecovirimat) To Treat Monkeypox in Central African Republic

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NEW YORK, July 29, 2021 (GLOBE NEWSWIRE) -- SIGA Technologies, Inc. (SIGA) (NASDAQ: SIGA), a commercial-stage pharmaceutical company focused on the health security market, today announced that it has entered into a collaboration with Oxford University in the United Kingdom (UK) to provide TPOXX® (tecovirimat) under an expanded access protocol to treat individuals affected by monkeypox in the Central African Republic (CAR). Under the agreement, Oxford University will sponsor the protocol and study in CAR, and SIGA will provide up to 500 courses of TPOXX (tecovirimat) at no cost.

The Institut Pasteur of Bangui ("IPB"), a research foundation established in CAR in 1961, will act as coordinator and be responsible for oversight and conduct of the study in CAR including managing the investigational sites, hosting the clinical trial database and performing the biological testing. The Ministry of Health and Population of CAR ("Ministry") will be responsible for the administration of TPOXX (tecovirimat) to patients with monkeypox infection at the selected investigational sites.

"Since the cessation of routine smallpox immunization in Central Africa, the region appears to be experiencing more outbreaks of monkeypox, a significant disease with mortality rates that can be up to 5 - 10% and that often disproportionately impacts children in rural areas," said Dennis Hruby, Chief Scientific Officer of SIGA Technologies. "SIGA is proud to provide TPOXX (tecovirimat) as a treatment for this public health challenge under an expanded access protocol, as we believe it may be an important approach to addressing the growing challenge of monkeypox in Central Africa."

In addition to providing TPOXX to this study, SIGA is seeking inclusion of treatment of monkeypox in the label indication as it works with the European Medicines Agency (EMA) to obtain regulatory approval for oral tecovirimat (marketed as TPOXX in the United States where that brand name has been approved). The company anticipates EMA approval of tecovirimat in late 2021 or early 2022 and has requested a label indication that includes treatment of smallpox, monkeypox, cowpox, and complications due to vaccinia vaccination.

"The Ministry of Health and Population, which oversees the study and management of monkeypox cases in the Central African Republic, is pleased to be participating in this important study," said Emmanuel Rivalyn Nakouné Yandoko, Scientific Director of the Institut Pasteur de Bangui, which plays a key role as a consultative institution for the Ministry of Health in CAR and is collaborating with the Ministry on this study.

Piero Olliaro, Professor of Infectious Diseases of Poverty and Director of Science at the International Severe Acute Respiratory and emerging Infection Consortium (ISARIC) – whose Global Support Centre is hosted by the University of Oxford - said "Monkeypox is a vastly neglected disease that attracts little attention and inadequate research investments. We are grateful that SIGA is making tecovirimat, which is approved in the United States for the treatment of smallpox, available under expanded access conditions to the Ministry of Health of CAR and are pleased that the company is working to extend the indications of tecovirimat to include monkeypox and other orthopoxviruses."

ISARIC is working with collaboratively with Institut Pasteur Bangui and the Ministry of Health to train health personnel and optimizing delivery and monitoring of tecovirimat treatment. Although not a formal clinical trial, the expanded access program will be conducted following good clinical practices, providing important insights into the effects of tecovirimat when delivered in real-life conditions."

Monkeypox is a contagious disease caused by infection with monkeypox virus, a virus closely related to variola virus, which causes smallpox. Monkeypox is characterized by severe flu-like symptoms and a rash of pus-filled pocks that may cover the whole body. The rash may not occur until approximately two weeks after exposure to the virus, making it difficult to diagnose initially, and, if not fatal, the disease may last nearly a month.. Almost all infections result from exposure to infected animals, although person-to-person transmission is possible. Most cases occur in Central and West African countries, but infections have been documented outside of Africa, including cases in the United States just this month (July 2021) and previously (2003), UK (2018, 2019), and Israel (2018). In comparison to West African strains, infections with Central African strains are typically more severe and more likely to be fatal (1 – 10%). The incidence of disease is likely to continue to increase, both within Africa and elsewhere, as protective immunity in the population decreases. This decreased immunity is due in part to cessation of vaccination for smallpox, which provided cross-reactive immunity to monkeypox, following the eradication of smallpox in 1980.

On July 2018, the U.S. Food and Drug Administration (FDA) approved the oral formulation of TPOXX (tecovirimat) for the treatment of smallpox to mitigate the impact of a potential outbreak or bioterror attack. TPOXX (tecovirimat), a small molecule, is the first therapy specifically approved for this indication, and was developed through funding and collaboration with Biomedical Advanced Research and Development Authority at the U.S. Department of Health and Human Services, as well as early stage development supported by the National Institutes of Health, U.S. Centers for Disease Control and Prevention, and the Department of Defense. In 2020, SIGA submitted an application for marketing authorization to the European Medicines Agency (EMA) that includes a broader label indication including the treatment of orthopox indications, including monkeypox, cowpox, and vaccinia complications in addition to smallpox. Approval is expected in late 2021 or early 2022.

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® (tecovirimat) also known as 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 stockpile of 1.7 million courses in the Strategic National Stockpile under Project BioShield. The oral formulation of TPOXX was approved by the FDA for the treatment of smallpox in adults and children weighing more than 13 kg on July 13, 2018. In September 2018, SIGA signed a new contract with Biomedical Advanced Research and Development Authority (BARDA) for additional procurement and development related to both oral and intravenous formulations of TPOXX (tecovirimat). For more information about SIGA, please visit www.siga.com.

ABOUT OXFORD UNIVERSITY AND ISARIC

ISARIC is a global federation of clinical research networks, providing a proficient, coordinated, and agile research response to outbreak-prone infectious diseases. ISARIC's purpose is to prevent illness and deaths from infectious diseases outbreaks. For more information about ISARIC, please visit www.isaric.org.

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.

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