SIGA Supplies TPOXX® (Tecovirimat) as Compassionate Treatment for Monkeypox Case in the United Kingdom

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NEW YORK, June 30, 2021 (GLOBE NEWSWIRE) -- SIGA Technologies, Inc. (SIGA) (NASDAQ: SIGA), a commercial-stage pharmaceutical company focused on the health security market, today announced that it provided TPOXX® (tecovirimat) to Liverpool University Hospitals NHS Foundation Trust, in the United Kingdom (UK). TPOXX, which is approved in the United States for the treatment of smallpox, was delivered to Liverpool for compassionate treatment for a patient confirmed to be infected with monkeypox.

SIGA has previously provided TPOXX on a named patient basis for the treatment of several cases of adverse events from vaccination with or accidental exposure to vaccinia virus, as well as to treat several patients infected with cowpox and a recent laboratory acquired vaccinia virus infection. One of these cases was recently published in the New England Journal of Medicine, where TPOXX was used to treat a patient in London, UK, infected with cowpox[1]. 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.

“As we undergo regulatory review in the EU and Canada for an expanded label for TPOXX, we continue to provide TPOXX as a compassionate use treatment for monkeypox, cowpox, and vaccinia complications,” said Phil Gomez, CEO of SIGA Technologies, “It is becoming clear TPOXX will be an important tool to treat these diseases throughout the world, and we are committed to expanding our regulatory approvals and provide access for patients.”

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 the disease may last nearly a month in total if not fatal. Almost all infections are contracted by exposure to infected animals, although person-to-person transmission is possible. Most cases occur in Central and West African countries where it is endemic, but infections have been documented outside of Africa; in the United States in 2003, UK (2018, 2019), and Israel (2018). 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 following eradication of smallpox in 1980, which had provided some degree of cross-reactive immunity to monkeypox.

On July 2018, the U.S. Food and Drug Administration (FDA) approved the oral formulation of TPOXX (tecovirimat) for the treatment of smallpox. TPOXX (tecovirimat), a small molecule, was 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. TPOXX is stockpiled by the U.S. Government to mitigate the impact of a potential outbreak or bioterror attack.

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 Smallpox[2]

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 currently routine vaccinations are not administered for people given the 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. 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.

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] Orbital Cowpox. Miles Kiernan and Nikolaos Koutroumanos. June 10, 2021, N Engl J Med 2021; 384:2241, DOI: 10.1056/NEJMicm2033620
[2] http://www.mayoclinic.org/diseases-conditions/smallpox/basics/definition/con-20022769

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