SIGA Announces Oncology Collaboration with KaliVir Immunotherapeutics

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SIGA to Supply TPOXX® to Support KaliVir's Oncolytic Vaccinia Clinical Immunotherapy Program

NEW YORK, July 15, 2022 (GLOBE NEWSWIRE) -- SIGA Technologies, Inc. (SIGA) (NASDAQ: SIGA), a commercial-stage pharmaceutical company focused on the health security market, today announced a collaboration with KaliVir Immunotherapeutics to make TPOXX® (tecovirimat) available for use with KaliVir's proprietary oncolytic vaccinia immunotherapy platform. This novel oncolytic platform includes multiple proprietary genetic modifications that can be combined to generate a unique oncolytic virus that has been optimized for systemic delivery and anti-tumor immune stimulation. Under this partnership, SIGA is providing its TPOXX oral capsules to support future clinical programs.

"KaliVir is an innovator in the creation of oncolytic viral immunotherapies, and we are excited to enter into this collaboration with them," said Dr. Phil Gomez, CEO of SIGA. "TPOXX is a powerful antiviral drug to vaccinia and allows the safe use of higher doses of vaccinia vectors; there is also the potential it could increase immunotherapeutic outcomes. This collaboration helps bring new levels of assurance to physicians, regulators, and especially patients receiving these promising investigational therapies."

"We are pleased to announce this collaboration with SIGA Technologies," said Helena Chaye, Ph.D., J.D., CEO of KaliVir. "Pairing oncolytic immunotherapies with an effective antiviral agent is a critical part of the development of new treatments, and we look forward to enhancing our groundbreaking oncolytic immunotherapy programs with the support of SIGA's TPOXX."

On July 13, 2018, the U.S. 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 preclinical studies, TPOXX has been shown to be active against most orthopoxviruses, including vaccinia (published in NEJM, 2018). The unique mechanism of action of TPOXX coupled with published efficacy in animal studies, make it an important addition to development programs focused on vaccinia-based cancer therapies. In 2020, SIGA entered into numerous collaborations, including a partnership with Turnstone Biologics to supply TPOXX to support Turnstone's clinical oncolytic vaccinia immunotherapy programs. In 2021, SIGA entered into a preclinical research collaboration with Bioarchitech to investigate TPOXX enabling higher doses of vaccinia vectors when used in combination with Bioarchitech's oncolytic vaccinia-based immunotherapy platform.

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 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. Oral tecovirimat received approval from the European Medicines Agency (EMA) in 2022. The EMA approval includes 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. For more information about SIGA, please visit www.siga.com.

ABOUT KALIVIR IMMUNOTHERAPEUTICS.

KaliVir Immunotherapeutics is a privately held biotech company developing cutting-edge, next-generation oncolytic viral immunotherapy programs. The company has developed a unique vaccinia virus-based platform that can generate potent novel oncolytic vaccinia viruses with modifications to maximize viral replication and to enhance intravenous delivery and spread (Vaccinia Enhanced Template "VET" Platform). VET™ platform utilizes the large transgene capacity of the vaccinia virus to deliver therapeutics matched to tumor immunophenotypes to stimulate patients' immune systems and modify the tumor microenvironment. KaliVir's oncolytic product candidates are designed to be safe, potent and systemically deliverable to treat cancer patients across multiple tumor types. KaliVir is in the process of advancing multiple therapeutic candidates toward the clinic. For more information, please visit www.kalivir.com.

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 U.S. government and no official endorsement should be inferred. The information contained on the websites referenced herein is not incorporated by reference into this press release.

Contacts:

Investor Contact
Laine Yonker, Edison Group
lyonker@edisongroup.com

Michael Crawford, Edison Group
mcrawford@edisongroup.com

KaliVir Immunotherapeutics

Paul Youm
Dir. Business Development
paul.youm@kalivir.com

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