



SIGA Announces Creation of Joint Procurement Mechanism by European Commission with Anticipated Initial Orders of Approximately \$18 Million for Oral TPOXX® (Tecovirimat) by Participating Countries

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NEW YORK, Oct. 23, 2023 (GLOBE NEWSWIRE) -- SIGA Technologies, Inc. (SIGA) (NASDAQ: SIGA), a commercial-stage pharmaceutical company focused on the health security market, today announced the creation by the European Commission's DG [HERA](#) (Health Emergency Preparedness and Response Authority) of a joint procurement mechanism under which 13 participating countries from the European Union (EU) and the European Free Trade Association (EFTA) can efficiently order oral TPOXX. Based on commitments from EU member countries, it is currently anticipated that \$18 million in approximate value of oral TPOXX will be initially ordered by EU countries under this mechanism within the next 60 days. Orders through the joint procurement mechanism will result in country-level procurement of oral TPOXX. Under the joint procurement mechanism, countries in the EU will acquire courses of oral TPOXX in the near term, and be able to efficiently order additional courses of oral TPOXX in the future as long as minimum quantity thresholds are met. Separately, as announced in September of 2022, the European Commission procured oral TPOXX through the funding of a direct purchase. Both transactions were coordinated by SIGA and its international promotion partner, Meridian Medical Technologies, LLC.

"With the creation of a joint procurement mechanism, there are now multiple paths in Europe for efficient procurement of oral TPOXX," said Phil Gomez, CEO of SIGA. "These protocols, through which every country in the EU can access oral TPOXX, highlight the importance of addressing the long-term impact and risks of orthopox viruses such as smallpox and monkeypox."

Orders under the joint procurement mechanism are expected to bring total TPOXX orders in 2023 to approximately \$164 million. A substantial percentage of these orders are expected to be delivered in 2023. As such, as previously disclosed, 2023 pre-tax operating income is expected to be between \$90 million and \$100 million.

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, and the IV formulation was approved for the same indication in 2022. The full label is available by [clicking here](#). Oral tecovirimat received approval from the European Medicines Agency (EMA) and the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom in 2022. The EMA and UK approvals include 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 Administration for Strategic 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

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, delivering products to the Strategic Stockpile, the enforceability of our procurement contracts, such as the 19C BARDA Contract (the "BARDA Contract"), with BARDA, the impact of the COVID pandemic and responding to the global outbreak of monkeypox. The words or phrases "can be," "expects," "may affect," "may depend," "believes," "estimate," "project" and similar words and phrases are intended to identify such forward-looking statements. 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. 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 BARDA elects, in its sole discretion as permitted under the BARDA Contract, not to exercise all, or any, of the remaining unexercised options under those contracts, (ii) the risk that SIGA may not complete performance under the BARDA Contract on schedule or in accordance with contractual terms, (iii)

the risk that the BARDA Contract, the current Department of Defense procurement contract or PEP Label Expansion R&D Contract (as defined in the Form 10-Q) 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 continue 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 of disruptions to 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 adversely affect SIGA's business, and (xv) risks associated with responding to the current monkeypox outbreak, as well as the risks and uncertainties included in Item 1A "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2022 and SIGA's subsequent filings with the Securities and Exchange Commission. SIGA urges investors and security holders to read those documents free of charge at the SEC's website at <http://www.sec.gov>. All such forward-looking statements are current only as of the date on which such statements were made. SIGA does not undertake any obligation to update publicly any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

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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