SIGA

Press Release

Interim Results from STOMP Study of SIGA's Tecovirimat in Treatment of Mpox Announced

- Interim analysis shows that tecovirimat did not improve time to lesion resolution compared to placebo in adults with mild to moderate clade II mpox
- Study stopped enrolling patients in all study arms
- Results affirm tecovirimat's strong safety profile
- Efficacy in patients with more severe disease not assessed in study

NEW YORK, December 10, 2024 (GLOBE NEWSWIRE) -- The National Institutes of Health's (NIH) National Institute of Allergy and Infectious Diseases (NIAID) today announced results from an interim analysis of the Study of Tecovirimat for Human Mpox Virus (STOMP) clinical trial (NCT05534984). NIAID reported that SIGA's tecovirimat, a highly targeted antiviral treatment, did not demonstrate efficacy in time to skin and mucosal lesion resolution compared to placebo in patients with mild to moderate clade II mpox. Based on this and additional analyses, the study Data Safety and Monitoring Board (DSMB) recommended to stop enrolling patients in the randomized arms of the study. NIAID accepted this recommendation and subsequently decided to take a similar action in the open label arm of this study, which included severe and at-risk of developing severe disease patients. Data analysis is not yet complete for primary endpoint subgroups and detailed secondary and exploratory endpoints.

"Antivirals are most effective when administered early in the course of an infection and tend to demonstrate the greatest benefit in patients with more severe disease. The STOMP results are not unexpected as the study design was similar to the PALM007 study except it was in patients with mild to moderate clade II mpox compared to patients with clade I mpox. It is important to note that approximately 75% of mpox patients in the randomized arms of the STOMP trial received tecovirimat more than five days after symptom onset, and higher risk patients were included in an open-label arm," stated Diem Nguyen, Chief Executive Officer.

Tecovirimat, also known as TPOXX, was developed in partnership with the U.S. Government and approved by the U.S. Food and Drug Administration to treat smallpox—a virus closely related to, but far more serious than, mpox. TPOXX was approved in 2018 based on data from 12 clinical trials of oral TPOXX in 700 healthy human volunteers, which showed no drug-related serious adverse events. Four pivotal trials in non-human primates (NHPs) and two pivotal trials in rabbits demonstrated that TPOXX significantly reduced both mortality and viral load in NHP infected with mpox virus and in rabbits infected with rabbitpox virus. The results of the animal efficacy studies were published in the July 5, 2018 issue of the *New England Journal of Medicine*.

"Tecovirimat's mechanism of action is driven by halting viral transmission. Once virus is present in the system, the body's natural immune system plays a central role in clearing it, typically within two to four weeks in immune competent patients. Research results thus far indicate that early treatment with tecovirimat including post-exposure prophylaxis and treatment in severe cases may offer the greatest potential for patient benefit," stated Dennis Hruby, Chief Scientific Officer.

Additionally, in this study, tecovirimat exhibited a safety profile comparable to placebo. These safety results are consistent with prior studies and further support the strong safety profile that has been observed with tecovirimat over the past 15 years.

Dr. Nguyen continued, "We thank our partners, the National Institute of Allergy and Infectious Diseases (NIAID) and the National Institutes of Health (NIH), the patients who participated in this trial, and the investigators who supported this trial. Their unwavering dedication to public health has been instrumental in advancing our understanding of mpox and tecovirimat."

Three randomized clinical trials, UNITY (Switzerland, Brazil, Argentina), Platinum-CAN (Canada), and EPOXI (EU), are enrolling mpox patients. Given the STOMP and PALM007 results and the design similarities across these mpox trials, the Company believes these ongoing trials are likely to yield similar results.

About the STOMP Clinical Trial in Mpox

The STOMP study is a randomized, placebo-controlled, double-blind study to evaluate the safety and efficacy of tecovirimat for the treatment of people with laboratory-confirmed or presumptive mpox disease. Beginning in September 2022, the study enrolled participants with mpox from Argentina, Brazil, Japan, Mexico, Peru, Thailand, and the United States, including Puerto Rico, who had symptoms for less than 14 days. Participants were randomly (2:1) assigned to receive tecovirimat or a placebo for 14 days. The number of capsules and frequency of dosage were based on patient weight. Participants with severe disease, certain skin conditions, or significantly suppressed immune systems received open-label tecovirimat rather than being randomized. The study monitored participants' safety across randomized and open label arms. In the randomized arms, STOMP examined the time to full mpox lesion resolution, viral clearance, and study participants' reports of pain. Participants were followed for 28 days with a study site visit at day 29 and then again at day 57 for possible recrudescence of infection.

About SIGA

SIGA Technologies (SIGA) (NASDAQ: SIGA) is a commercial-stage pharmaceutical company and leader in global health focused on the development of innovative medicines to treat and prevent infectious diseases. With a primary focus on orthopoxviruses, we are dedicated to protecting humanity against the world's most severe infectious diseases, including those

that occur naturally, accidentally, or intentionally. Through partnerships with governments and public health agencies, we work to build a healthier and safer world by providing essential countermeasures against these global health threats. Our flagship product, TPOXX® (tecovirimat), is an antiviral medicine approved in the U.S. and Canada for the treatment of smallpox and authorized in Europe and the UK for the treatment of smallpox, mpox (monkeypox), cowpox, and vaccinia complications. For more information about SIGA, visit www.siga.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 efficacy of tecovirimat to treat mpox in certain patient populations and the results of ongoing mpox clinical studies. Forward-looking statements include statements regarding our future financial position, business strategy, budgets, projected costs, plans and objectives of management for future operations. The words "may," "continue," "estimate," "intend," "plan," "will," "believe," "project," "expect," "seek," "anticipate," "could," "should," "target," "goal," "potential" and similar expressions may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. 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 75A50118C00019 BARDA Contract (the "BARDA Contract"), not to exercise the remaining unexercised option under the BARDA Contract, (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 or U.S. Department of Defense contracts are modified or canceled at the request or requirement of, or SIGA is not able to enter into new contracts to supply TPOXX to, 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 target timing for deliveries of product to customers, and the recognition of related revenues, are delayed or adversely impacted by the actions, or inaction, of contract manufacturing organizations, or other vendors, within the supply chain, or due to coordination activities between the customer and supply chain vendors, (vii) the risk that SIGA or its collaborators will not obtain appropriate or necessary governmental approvals to market these or other potential products or uses, (viii) the risk that SIGA may not be able to secure or enforce sufficient legal rights in its products, including intellectual property protection, (ix) 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, (x) 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, (xi) the risk that the volatile and competitive nature of the biotechnology industry may hamper SIGA's efforts to develop or market its products, (xii) 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, (xiii) the effect of federal, state, and foreign regulation, including drug regulation and international trade regulation, on SIGA's businesses, (xiv) 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, (xv) risks associated with actions or uncertainties surrounding the debt ceiling, (xvi) the risk that the U.S. or foreign governments' responses (including inaction) to national or global economic conditions or infectious diseases, are ineffective and may adversely affect SIGA's business, and (xvii) risks associated with responding to an mpox 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, 2023 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.

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