SIGA

News Release

Topline Results from PALM 007 Study of SIGA's Tecovirimat in Treatment of Mpox Released

- Preliminary analysis shows the study did not reach statistical significance on its primary endpoint of tecovirimat being superior to placebo in lesion resolution for all patients
- Results suggest tecovirimat provides clinical benefit vs. placebo in two important patient populations: those treated early and those with severe disease
- Results affirm tecovirimat's strong safety profile
- Multiple additional clinical trials evaluating tecovirimat for mpox continue

NEW YORK, Aug. 15, 2024 (GLOBE NEWSWIRE) -- The National Institutes of Health's (NIH) National Institute of Allergy and Infectious Diseases (NIAID) today announced topline results from a preliminary analysis of the PALM 007 (Tecovirimat for Treatment of Monkeypox Virus) clinical trial (NCT05559099). NIAID reported that the study did not meet its primary endpoint of a statistically significant improvement in time to lesion resolution within 28 days post-randomization for patients in the Democratic Republic of the Congo (DRC) with monkeypox (mpox), who were administered SIGA's tecovirimat, a highly targeted antiviral treatment, versus placebo. All patients in this study were hospitalized for the entire duration of treatment. This study was not a registration study conducted under an U.S. FDA Investigational New Drug Application.

A meaningful improvement was observed in patients receiving tecovirimat whose symptoms began seven days or fewer before randomization and in those with severe or greater disease, defined by the World Health Organization (WHO) as having 100 or more skin lesions. While more analysis is required, the Company believes these data support further trials to assess the potential benefit of tecovirimat in those who present to medical care soon after symptoms and in those with severe disease.

"These data showing maximum benefit in patients treated early and with severe disease are entirely consistent with the mechanism of action of tecovirimat and with the studies in animals that led to U.S. FDA approval of this medicine for smallpox, a virus closely related to monkeypox virus, but which produces much more severe illness. We believe these data warrant further investigation and support our view that post exposure prophylaxis will be vital for treatment of severe cases of mpox and all cases of smallpox," stated Dennis Hruby, Chief Scientific Officer.

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

"We are highly encouraged by the PALM 007 study results which showed that tecovirimat is safe and offers potential benefit to important groups of patients with mpox disease, particularly those with severe disease and those who sought treatment early. As with other acute viral infections, patients benefit the most when antiviral treatment is administered as soon as possible after infection. Missing the primary endpoint is not entirely unexpected given that the study population was hospitalized during

the duration of treatment receiving a high level of supportive care, and since many presented for treatment more than a week after their illness started," stated Diem Nguyen, Chief Executive Officer.

"SIGA and the National Institute of Allergy and Infectious Diseases (NIAID), the trial sponsor, are in the process of thoroughly analyzing the data to gain a comprehensive understanding of the results and potential implications. We look forward to future research on the impact of early treatment on improving outcomes in mpox patients in real world settings. Our team is committed to leveraging these findings to investigate effective treatment regimens for mpox and other infectious diseases."

As background, the PALM 007 study was part of a globally coordinated initiative to address the 2022 mpox outbreak occurring in the DRC and around the world. It was, therefore, designed with important humanitarian considerations, such as allowing patients at varying stages of disease, age, health, among other factors, to participate in the trial. To ensure study data could be collected accurately and that patients had access to food, all patients in the study were hospitalized for the duration of treatment, and therefore received a level of care unavailable to most mpox patients in real world situations. In PALM 007, patients in the placebo arm had much more favorable outcomes than those in the observational studies from the DRC that were used to plan this trial, which could have reduced the measured benefit of tecovirimat compared to placebo. The exact impact of this controlled environment on the trial results is not yet known.

Additional studies are being conducted by trial sponsors around the world and are expected to help the Company gain a deeper understanding of the potential for tecovirimat to benefit patients with mpox. Four randomized clinical trials are currently enrolling patients, including STOMP (U.S. and other countries), UNITY (Switzerland, Brazil, Argentina), Platinum-CAN (Canada), and EPOXI (EU). Because the PALM 007 study differs in significant respects from these other studies, data from these studies will help SIGA to understand whether the PALM 007 results were influenced by factors such as trial design, patient population, medical protocols, disease clade, or other variables. For example, compared to PALM 007, the STOMP, UNITY, Platinum-CAN, and EPOXI trials to date have enrolled no children and a much higher percentage of immunocompromised patients, such as those living with HIV.

Dr. Nguyen continued, "We thank all our partners, the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), and Institut National de la Recherche Biomédicale (INRB), for their unwavering support. We are also grateful to all the patients who participated in this trial and the investigators who supported this trial in the DRC. Their dedication and commitment to public health have been critical in gaining a greater understanding of tecovirimat."

About the PALM 007 Clinical Trial in Mpox

The PALM 007 study is a randomized, placebo-controlled, double-blind trial to evaluate the safety and efficacy of oral tecovirimat to treat mpox virus disease in combination with standard of care (SOC). Participating patients were diagnosed with laboratory-confirmed mpox as determined by a PCR test within 48 hours of screening in the DRC. There were no age restrictions, but patients were required to weigh more than three kilograms (approximately 6.6 pounds). Patients were randomly (1:1) assigned to receive oral tecovirimat plus SOC or placebo plus SOC for 14 days. The number of capsules and frequency of dosage were based on patient weight. Patients receiving tecovirimat remained hospitalized for at least two weeks and were followed for 28 days with an optional visit at Day 59 for

long-term assessment. The primary measure of efficacy was the number of days to the first day on which all lesions on the total body were scabbed or desquamated or a new layer of epidermis had formed up to 28 days.

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 potential benefit of tecovirimat in certain mpox patients or for use of tecovirimat as a post-exposure prophylaxis. The words or phrases "can be," "expects," "may affect," "may depend," "believes," "estimate," "will", "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 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 TPOXX for smallpox or additional 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.

Contacts:
Suzanne Harnett
sharnett@siga.com

and

Investors
Jennifer Drew-Bear, Edison Group
Jdrew-bear@edisongroup.com

Media
Jenna Urban, Berry & Company
jurban@berrypr.com