

TEPOXX (tecovirimat) Approved in Japan for the Treatment of Orthopoxviruses

- Regulatory decision marks first approval in Japan of an antiviral for the treatment of orthopoxviruses including smallpox, mpox and cowpox
- Japan Biotechno Pharma Co., Ltd. engaged as exclusive distributor to supply TEPOXX to Japan's national stockpile
- Comprehensive data package demonstrates strong safety profile and robust preclinical efficacy

New York, NY (January 2, 2025) - SIGA Technologies, a commercial stage pharmaceutical company, announced today that its antiviral treatment TEPOXX (tecovirimat 200 mg capsules), marketed as TPOXX in the United States, has received regulatory approval in Japan for the treatment of smallpox, mpox, cowpox, as well as complications following smallpox vaccination in adults and pediatric patients weighing at least 13 kg. TEPOXX is the first antiviral therapy approved by the Pharmaceuticals and Medical Devices Agency (PMDA), in collaboration with the Japan Ministry of Health, Labour and Welfare, for the treatment of orthopoxviruses.

In partnership with Japan Biotechno Pharma, SIGA's exclusive distributor in Japan, SIGA has delivered an order of TEPOXX to help build Japan's strategic national stockpile.

"The approval of TEPOXX in Japan marks another significant milestone in our mission to expand access to this critical antiviral treatment worldwide to support an effective response to an orthopoxvirus outbreak. As a capsule with a long shelf life, TEPOXX can easily be deployed in time sensitive emergencies," said Diem Nguyen, Chief Executive Officer. "We are grateful for the close collaboration with the Japanese regulatory authorities and strong partnership with Japan Biotechno Pharma that made this accomplishment possible. This approval highlights the importance of stockpiling effective antiviral therapies as a cornerstone of innovative solutions to safeguard public health against serious and potentially devastating infectious diseases, such as smallpox."

The Japanese approval is based on data from 15 clinical trials of oral TEPOXX in over 800 healthy volunteers, including a pivotal repeat-dose phase 1 pharmacokinetics (PK) trial involving 20 healthy volunteers conducted in Japan. These studies showed no drug-related serious adverse events and quantifiable PK within efficacious dose ranges. Four pivotal studies in non-human primates (NHPs) and two pivotal studies in rabbits demonstrated that TEPOXX significantly reduced both mortality and viral load. The results of the animal efficacy studies were published in the July 5, 2018 issue of the [New England](#)

[*Journal of Medicine*](#). TEPOXX has also been studied in NHPs infected with variola virus, the virus which causes smallpox, where TEPOXX demonstrated improved survival and reduction in lesions.

“This milestone reflects years of dedication and scientific innovation,” said Dennis Hruby, Ph.D., Chief Scientific Officer. “TEPOXX was designed with a deep understanding of orthopoxviruses and has the potential to deliver an effective treatment option for managing these potentially devastating diseases. We are proud to see our work contribute to enhanced preparedness and public health resilience in Japan.”

TEPOXX is a highly targeted small-molecule antiviral that inhibits the VP37 protein found on the surface of all orthopoxviruses. By preventing the virus from exiting infected cells, TEPOXX slows the spread of the infection, enabling the immune system to clear the virus.

TPOXX is approved in the U.S. and Canada for the treatment of smallpox. In the European Union and United Kingdom, marketed as Tecovirimat-SIGA, it is approved for the treatment of smallpox, mpox, cowpox, and to treat complications following smallpox vaccination.

ABOUT SIGA

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, the UK, and Japan 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 SIGA’s future business development and plans including with respect to future sales of TEPOXX in Japan. 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.

Contacts:

Suzanne Harnett
sharnett@sigacom

and

Investors

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

Media

Holly Stevens, Berry & Company
hstevens@berrypr.com