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Tonix Pharmaceuticals and Bilthoven Biologicals to Collaborate on Advancing Development of Tonix's Mpox Vaccine, TNX-801

World Health Organization declared spread of mpox in multiple African countries a public health emergency of international concern (PHEIC) for the second time in two years

Worldwide availability and affordability of single-dose mpox vaccine with durable protection will be required to address global health emergency

The newest Clade 1 strain represents a new global threat with mortality up to 10%

Bilthoven Biologicals to develop manufacturing processes in preparation for potential GMP manufacturing

CHATHAM, N.J., Aug. 26, 2024 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix), a fully-integrated biopharmaceutical company with marketed products and a pipeline of development candidates, and Bilthoven Biologicals (BBio), part of the world's largest vaccine manufacturer the Cyrus Poonawalla Group, which includes the Serum Institute of India, today announced a collaboration to advance TNX-801, Tonix's mpox vaccine candidate. TNX-801 (recombinant horsepox virus) is a live replicating, attenuated virus vaccine based on horsepox in preclinical development to prevent mpox and smallpox.

TNX-801 is based on technology that has the potential to be used as a viral vector platform from which recombinant versions can be developed to protect against other infectious diseases. BBio is a global vaccine company, producing prophylactic vaccines as well as vaccines for therapeutic use. BBio has been selected by the European Union for its pandemic preparedness program of 'ever warm' vaccine manufacturing companies.

TNX-801 has demonstrated in animal models to provide immune protection with better tolerability than vaccines based on 20th century vaccinia viruses. Preclinical studies have shown positive efficacy data, demonstrating that TNX-801 protected non-human primates against lethal challenge with intratracheal Clade 1 monkeypox virus. After a single dose vaccination, TNX-801 prevented clinical disease and lesions and decreased shedding in the mouth and lungs of non-human primates. These findings are consistent with mucosal immunity and suggest the ability to block forward transmission.

On August 14, 2024, the World Health Organization (WHO) determined that the upsurge of mpox in a growing number of countries in Africa constitutes a public health emergency of

international concern, the second such declaration in the past two years called in response to an mpox outbreak. The current outbreak was caused by Clade 1 monkeypox virus, while the 2022 outbreak was caused by Clade 2 monkeypox virus. The global mpox outbreak from Clade 2, which commenced in 2022, has affected over 90,000 persons in countries where mpox had previously not been endemic, including Europe and the U.S. The spread of Clade 2b mpox in 2022 underscores the pandemic potential of the disease. In several Central African countries, including the Democratic Republic of the Congo, mpox is currently endemic, with the Clade 1 showing a mortality rate of up to 10%.

“The recent mpox outbreak exemplifies precisely why we built the pandemic preparedness facility at BBio,” said Jurgen Kwik, Chief Executive Officer of Bilthoven Biologicals. “The establishment of the 'ever-warm' facility for pandemic preparedness underscores the critical importance of readiness in the face of global health emergencies, such as mpox. This collaboration encapsulates the essential role of the facility in bolstering pandemic preparedness and response capabilities."

“We look forward to collaborating with BBio and to accelerating the development of our vaccine candidate to prevent mpox,” said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. “TNX-801 is administered with a single dose, which we believe will improve acceptance and eliminate partial vaccination compared to the current two-dose regimens. We believe TNX-801 can be rapidly scaled up for manufacturing and can be distributed and stored without a costly and cumbersome ultra-cold supply chain. TNX-801 has the potential to make a global impact on mpox and the risk of smallpox because of its durable T-cell immune response, the potential to manufacture at scale, and the use of a lower dose than non-replicating vaccines.”

Dr. Lederman added, “The worldwide availability of an affordable, safe and effective single dose mpox vaccine is essential given the pandemic potential of the disease. Successful development of TNX-801 will establish the foundation for potentially expanding the viral vector platform, for which recombinant versions can be developed to protect against other infectious diseases and future outbreaks. Our TNX-1800 vaccine (recombinant horsepox virus expressing SARS-CoV-2 spike) in development to protect against COVID-19 was selected by the U.S. National Institutes of Health for Project NextGen.”

About TNX-801

TNX-801 (recombinant horsepox virus) is a live virus vaccine based on horsepox in pre-clinical development to prevent mpox and smallpox. Tonix reported positive preclinical efficacy data, demonstrating that TNX-801 vaccination protected non-human primates against lethal challenge with monkeypox.[1] Tonix has received official written response from a Type B pre-Investigational New Drug Application (IND) meeting with the U.S. Food and Drug Administration (FDA) to develop TNX-801 as a potential vaccine to protect against mpox disease and smallpox.[2] Tonix believes the FDA feedback provides a path to agreement on the design of a Phase 1 /2 study and the overall clinical development plan. More than 90,000 people contracted mpox globally. during the 2022-23 epidemic.[3] The June 2023 cluster of mpox in Chicago revealed breakthrough cases of the disease in individuals who had been vaccinated with the currently authorized non-replicating vaccine, which is administered in two doses.[4] In contrast, TNX-801 is delivered percutaneously with only one dose and therefore may achieve higher rates of community protection by eliminating drop-out between doses and limiting forward transmission. Moreover, relying on only one

approved mpox vaccine at present is a risk for the global supply chain that has already led to insufficient availability of vaccines to meet global health needs, especially in Africa. TNX-801 has the potential to make a global impact on mpox and the risk of smallpox because of its durable T-cell immune response, the potential to manufacture at scale, and the use of a lower dose than non-replicating vaccines.

[1]Noyce RS, et al. *Viruses*. 2023;15(2):356. https://doi.org/10.3390/v15020356
[2]TNX-801 PR pre-IND meeting 8/20/23: https://ir.tonixpharma.com/news-events/press-releases/detail/1417/tonix-pharmaceuticals-announces-results-of-pre-ind-meeting
[3]CDC. (2022-2023). Mpox Outbreak Global Map
https://www.cdc.gov/poxvirus/mpox/response/2022/world-map.html
[4]Faherty EA, et al. *MMWR Morb Mortal Wkly Rep*. 2023;72:696–698.
http://dx.doi.org/10.15585/mmwr.mm7225a6.

About Bilthoven Biologicals (BBio)

BBio is a Netherlands-based end-to-end vaccine manufacturer of viral and bacterial vaccines. The company has a long-standing track record in supplying vaccines to European markets and global health partners such as UNICEF, PAHO and WHO/GAVI. With the manufacturing of polio vaccines, BBio is key contributor to the worldwide program to eradicate polio. BBio is also acting as contract manufacturer of vaccines used as cancer treatment, which is registered and supplied to the European market for the treatment of bladder cancer.

BBio is a carve-out of the former Netherlands Vaccine Institute and was acquired by Serum Institute of India in 2012 and employs a little over 500 people. BBio is covering the full vaccine manufacturing value chain with its facilities in Bilthoven on Utrecht Science Park Bilthoven.

For more information, please visit www.bbio.nl

Tonix Pharmaceuticals Holding Corp.*

Tonix is a fully-integrated biopharmaceutical company focused on developing, licensing and commercializing therapeutics to treat and prevent human disease and alleviate suffering. Tonix recently announced the U.S. Department of Defense (DoD), Defense Threat Reduction Agency (DTRA) awarded it a contract for up to $34 million over five years to develop TNX-4200 small molecule broad-spectrum antiviral agents targeting CD45 for the prevention or treatment of infections to improve the medical readiness of military personnel in biological threat environments. Tonix owns and operates a state-of-the art infectious disease research facility in Frederick, MD. The company's Good Manufacturing Practice (GMP)-capable advanced manufacturing facility in Dartmouth, MA was purpose-built to manufacture TNX-801 and the GMP suites are ready to be reactivated in case of a national or international emergency. Tonix's development portfolio is focused on central nervous system (CNS) disorders. Tonix's priority is to submit a New Drug Application (NDA) to the FDA in the second half of 2024 for TNX-102 SL, a product candidate for which two statistically significant Phase 3 studies have been completed for the management of fibromyalgia. The FDA has granted Fast Track designation to TNX-102 SL for the management of fibromyalgia. TNX-102 SL is also being developed to treat acute stress

reaction. Tonix's CNS portfolio includes TNX-1300 (cocaine esterase), a biologic in Phase 2 development, designed to treat cocaine intoxication that has Breakthrough Therapy designation. Tonix's immunology development portfolio consists of biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is a humanized monoclonal antibody targeting CD40-ligand (CD40L or CD154) being developed for the prevention of allograft rejection and for the treatment of autoimmune diseases. Tonix also has product candidates in development in the areas of rare disease and infectious disease, including a vaccine for mpox, TNX-801. Tonix Medicines, our commercial subsidiary, markets Zembrace® SymTouch® (sumatriptan injection) 3 mg and Tosymra® (sumatriptan nasal spray) 10 mg for the treatment of acute migraine with or without aura in adults.

*Tonix's product development candidates are investigational new drugs or biologics and have not been approved for any indication.

Zembrace SymTouch and Tosymra are registered trademarks of Tonix Medicines. All other marks are property of their respective owners.

This press release and further information about Tonix can be found at www.tonixpharma.com.

Forward Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate," "expect," and "intend," among others. These forward-looking statements are based on Tonix's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, risks related to the failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; risks related to the failure to successfully market any of our products; risks related to the timing and progress of clinical development of our product candidates; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties; and substantial competition. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. Tonix does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in the Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the Securities and Exchange Commission (the "SEC") on April 1, 2024, and periodic reports filed with the SEC on or after the date thereof. All of Tonix's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements. The information set forth herein speaks only as of the date thereof.

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