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# **Tonix Pharmaceuticals Announces Grant by Medical CBRN Defense Consortium (MCDC) for Development of TNX-801, the Company's Single-Dose Mpox and Smallpox Vaccine Candidate**

*The World Health Organization (WHO) recently reaffirmed the spread of new clade Ib Mpox a public health emergency of international concern (PHEIC): second Mpox-related WHO PHEIC declaration in two years*

*Clade Ib Mpox cases detected in several countries in Central and Eastern Africa as well as China, Thailand, Singapore, India, England, parts of Europe and the Middle East, Canada and the United States*

*Tolerability of TNX-801 vaccination in immune-compromised animal models supports clinical development*

CHATHAM, N.J., March 10, 2025 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a fully-integrated biopharmaceutical company with marketed products and a pipeline of development candidates, today announced it has been awarded a grant from the Medical CBRN Defense Consortium (MCDC) to support the development of TNX-801 (recombinant horsepox virus, live vaccine). MCDC is a consortium of industrial, academic, and non-profit entities that supports the U.S. government in meeting military requirements for medical products to protect against chemical, biological, radiological and nuclear (CBRN) threats. TNX-801 is in development as an mpox and smallpox vaccine with the potential to be delivered via innovative alternative methods to improve patient compliance, ease of use and tolerability. The MCDC grant will allow for further comprehensive market analyses, target market identification and commercialization planning, including for both private and government markets.

“We are excited by the opportunity to collaborate with MCDC and are thankful for their support of our vaccine candidate,” said Seth Lederman, M.D., President, and Chief Executive Officer of Tonix. “TNX-801 offers an appealing target product profile, requiring just a single dose for durable, long-term protection, with favorable shipping and storage requirements. With a significant global unmet need, TNX-801 is in a strong position to make a potential impact towards preventing mpox and controlling mpox epidemics.”

TNX-801 is an attenuated live-virus vaccine based on synthesized horsepox that has been shown to provide single-dose immune protection against a monkeypox challenge with better tolerability than 20th century vaccinia live-virus vaccines in animals. TNX-801 has previously

been shown to protect animals against lethal challenge with intratracheal clade I monkeypox virus.<sup>1</sup> An outbreak of clade I mpox was declared a Public Health Emergency of International Concern (PHEIC) by the World Health Organization (WHO) in August of 2024 and reaffirmed in February 2025.<sup>2,3</sup> Starting from an outbreak in the Democratic Republic of the Congo, clade I mpox has spread to sixteen Central African Countries and outside of Africa, including in China, Thailand, Singapore, India, England, parts of Europe and the Middle East, Canada and the United States.<sup>4</sup>

### **Tonix Pharmaceuticals Holding Corp.\***

Tonix is a fully-integrated biopharmaceutical company focused on transforming therapies for pain management and vaccines for public health challenges. Tonix's development portfolio is focused on central nervous system (CNS) disorders. Tonix's priority is to advance TNX-102 SL, a product candidate for the management of fibromyalgia, for which an NDA was submitted based on two statistically significant Phase 3 studies for the management of fibromyalgia and for which a PDUFA (Prescription Drug User Fee act) goal date of August 15, 2025 has been assigned for a decision on marketing authorization. The FDA has also 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 and acute stress disorder under a Physician-Initiated IND at the University of North Carolina in the OASIS study funded by the U.S. Department of Defense (DoD). Tonix's CNS portfolio includes TNX-1300 (cocaine esterase), a biologic in Phase 2 development designed to treat cocaine intoxication that has FDA Breakthrough Therapy designation, and its development is supported by a grant from the National Institute on Drug Abuse. Tonix's immunology development portfolio consists of biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is an Fc-modified humanized monoclonal antibody targeting CD40-ligand (CD40L or CD154) being developed for the prevention of allograft rejection and for the treatment of autoimmune diseases. TNX-1500 has completed a positive Phase I trial. Tonix's infectious disease portfolio includes TNX-801, a vaccine in development for mpox and smallpox, as well as TNX-4200 for which Tonix has a contract with the U.S. DoD's Defense Threat Reduction Agency (DTRA) for up to \$34 million over five years. TNX-4200 is a small molecule broad-spectrum antiviral agent 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. Tonix Medicines, our commercial subsidiary, markets Zembrace<sup>®</sup> SymTouch<sup>®</sup> (sumatriptan injection) 3 mg and Tosymra<sup>®</sup> (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; their efficacy and safety have not been established 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](http://www.tonixpharma.com).

<sup>1</sup>Noyce RS, et al. *Viruses*. 2023 Jan 26;15(2):356. Doi: 10.3390/v15020356. PMID:

36851570; PMCID: PMC9965234

<sup>2</sup>WHO Press Release August 14, 2024. "WHO Director-General declares mpox outbreak a public health emergency of international concern". URL: [www.who.int/news/item/14-08-2024-who-director-general-declares-mpox-outbreak-a-public-health-emergency-of-international-concern](http://www.who.int/news/item/14-08-2024-who-director-general-declares-mpox-outbreak-a-public-health-emergency-of-international-concern) (accessed 8-15-24)

<sup>3</sup>McQuiston JH, et al. *U.S. Preparedness and Response to Increasing Clade I Mpox Cases in the Democratic Republic of the Congo*. 2024, MMWR Morbidity and Mortality Weekly Report: United States. p. 435-440

<sup>4</sup><https://www.cdc.gov/mpox/situation-summary/>

## **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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## Indication and Usage

Zembrace<sup>®</sup> SymTouch<sup>®</sup> (sumatriptan succinate) injection (Zembrace) and Tosymra<sup>®</sup> (sumatriptan) nasal spray are prescription medicines used to treat acute migraine headaches with or without aura in adults who have been diagnosed with migraine.

Zembrace and Tosymra are not used to prevent migraines. It is not known if Zembrace or Tosymra are safe and effective in children under 18 years of age.

## Important Safety Information

**Zembrace and Tosymra can cause serious side effects, including heart attack and other heart problems, which may lead to death. Stop use and get emergency help if you have any signs of a heart attack:**

- discomfort in the center of your chest that lasts for more than a few minutes or goes away and comes back
- severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
- pain or discomfort in your arms, back, neck, jaw or stomach
- shortness of breath with or without chest discomfort
- breaking out in a cold sweat
- nausea or vomiting
- feeling lightheaded

Zembrace and Tosymra are not for people with risk factors for heart disease (high blood pressure or cholesterol, smoking, overweight, diabetes, family history of heart disease) unless a heart exam shows no problem.

Do not use Zembrace or Tosymra if you have:

- history of heart problems
- narrowing of blood vessels to your legs, arms, stomach, or kidney (peripheral vascular disease)
- uncontrolled high blood pressure
- hemiplegic or basilar migraines. If you are not sure if you have these, ask your provider.
- had a stroke, transient ischemic attacks (TIAs), or problems with blood circulation
- severe liver problems
- taken any of the following medicines in the last 24 hours: almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, ergotamines, or dihydroergotamine. Ask your provider for a list of these medicines if you are not sure.

- are taking certain antidepressants, known as monoamine oxidase (MAO)-A inhibitors or it has been 2 weeks or less since you stopped taking a MAO-A inhibitor. Ask your provider for a list of these medicines if you are not sure.
- an allergy to sumatriptan or any of the components of Zembrace or Tosymra

Tell your provider about all of your medical conditions and medicines you take, including vitamins and supplements.

Zembrace and Tosymra can cause dizziness, weakness, or drowsiness. If so, do not drive a car, use machinery, or do anything where you need to be alert.

Zembrace and Tosymra may cause serious side effects including:

- changes in color or sensation in your fingers and toes
- sudden or severe stomach pain, stomach pain after meals, weight loss, nausea or vomiting, constipation or diarrhea, bloody diarrhea, fever
- cramping and pain in your legs or hips; feeling of heaviness or tightness in your leg muscles; burning or aching pain in your feet or toes while resting; numbness, tingling, or weakness in your legs; cold feeling or color changes in one or both legs or feet
- increased blood pressure including a sudden severe increase even if you have no history of high blood pressure
- medication overuse headaches from using migraine medicine for 10 or more days each month. If your headaches get worse, call your provider.
- serotonin syndrome, a rare but serious problem that can happen in people using Zembrace or Tosymra, especially when used with anti-depressant medicines called SSRIs or SNRIs. Call your provider right away if you have: mental changes such as seeing things that are not there (hallucinations), agitation, or coma; fast heartbeat; changes in blood pressure; high body temperature; tight muscles; or trouble walking.
- hives (itchy bumps); swelling of your tongue, mouth, or throat
- seizures even in people who have never had seizures before

The most common side effects of Zembrace and Tosymra include: pain and redness at injection site (Zembrace only); tingling or numbness in your fingers or toes; dizziness; warm, hot, burning feeling to your face (flushing); discomfort or stiffness in your neck; feeling weak, drowsy, or tired; application site (nasal) reactions (Tosymra only) and throat irritation (Tosymra only).

Tell your provider if you have any side effect that bothers you or does not go away. These are not all the possible side effects of Zembrace and Tosymra. For more information, ask your provider.

This is the most important information to know about Zembrace and Tosymra but is not comprehensive. For more information, talk to your provider and read the Patient Information and Instructions for Use. You can also visit <https://www.tonixpharma.com> or call 1-888-869-7633.

You are encouraged to report adverse effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.



Source: Tonix Pharmaceuticals Holding Corp.