January 29, 2020

Tonix Pharmaceuticals Presented Results from a Preclinical Study of TNX-801, a Potential Vaccine to Prevent Smallpox and Monkeypox, in a Poster Presentation at the 2020 American Society for Microbiology (ASM) Biothreats Conference

NEW YORK, Jan. 29, 2020 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, presented preclinical results of TNX-801 (live virus vaccine for percutaneous administration) to potentially prevent smallpox and monkeypox in a poster at the 2020 ASM Biothreats Conference held January 28-30, 2020 in Arlington, Va. The poster, titled “Synthetic Chimeric Horsepox Virus (scHPXV) Vaccination Protects Macaques from Monkeypox” includes preclinical safety and efficacy analyses of TNX-801. The poster can be found on the Scientific Presentations page of Tonix’s website.

Cynomolgus macaques (four per group) were vaccinated with either high dose or low dose TNX-801, TNX-1200 (live virus vaccine based on synthesized vaccinia, or sVACV), or vehicle control. The poster presentation reports that all animals (eight of eight) vaccinated with TNX-801 were fully protected with sterilizing immunity from a challenge with intra-tracheal monkeypox. In contrast, two of three evaluable animals vaccinated with TNX-1200, and all animals who received the vehicle control, developed monkeypox lesions after challenge. In addition, after a single vaccination, four of four animals vaccinated with high dose of TNX-801 and three of four animals vaccinated with a low dose of TNX-801 responded with a cutaneous reaction called a “take” that is a biomarker of protective immunity in immunocompetent individuals in campaigns to control smallpox contagion. In contrast, only one of three animals vaccinated with a low dose of TNX-1200 responded with a take. The vaccinations with TNX-801 or TNX-1200 were well tolerated. TNX-801 and TNX-1200 are in the preclinical and pre-Investigational New Drug (IND) application stage of development. Tonix is developing TNX-801 and TNX-1200 as potential smallpox preventing vaccines for the U.S. strategic national stockpile and as monkeypox preventing vaccines for areas where monkeypox is a growing problem.

About TNX-801 and TNX-1200

TNX-801 is a live virus vaccine based on synthesized horsepox (sHPXV). TNX-1200 is a live virus vaccine based on synthesized vaccinia (sVACV). HPXV virus is closely related to VACV vaccines. Molecular analysis suggests that TNX-801 is closer than modern vaccines

in DNA sequence[1,2] to the vaccine discovered and disseminated by Dr. Edward Jenner. Molecular analysis indicates that HPXV has “complete” left and right inverted terminal repeats (ITRs) while different VACV isolates have a variety of deletions in the left and right ITRs. Therefore, TNX-801 has additional genes, relative to VACV vaccines, that may play roles in host immune interactions and one or more or such proteins may serve as antigens for protective immunity. Both TNX-801 and TNX-1200 were assembled using synthetic DNA fragments[3]. TNX-1200 was based on a complete genome sequence of a laboratory isolate of VACV, including the terminal hairpin sequences and the repeat regions in the ITRs. The sequence of this laboratory isolate of VACV (Genbank Accession # MN974380) is very similar to the published sequence of VACV strain ACAM2000®[4]. Also deposited in Genbank are the TNX-1200 sequence (Accession # MN974381) and the TNX-801 sequence (Accession # KY349117.1).

[1]Schrick L et al. N Engl J Med. (2017) 377:1491.
[2]Qin *et al.* J. Virol. 89:1809 (2015).1Noyce RS et al, PLoS One. (2018) 13:e0188453.
[3]Noyce RS et al, PLoS One. (2018) 13:e0188453.
[4]ACAM2000 is a registered trademark of Emergent Product Development Gaithersburg Inc.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering and developing small molecules and biologics to treat psychiatric, pain and addiction conditions. Tonix’s lead product candidate, TNX-102 SL*, is in Phase 3 development as a bedtime treatment for posttraumatic stress disorder (PTSD) (trade name Tonmya**) and fibromyalgia. The Phase 3 RECOVERY trial (P302) in PTSD is currently enrolling and results from an interim analysis for a potential sample size adjustment are expected in the first quarter of 2020 and topline data are expected in the second quarter of 2020 if the sample size remains the same. TNX-102 SL for PTSD has U.S. Food and Drug Administration (FDA) Breakthrough Therapy Designation. The Company has started enrollment in the Phase 3 RELIEF trial in fibromyalgia. TNX-102 SL is also in development for agitation in Alzheimer’s disease and alcohol use disorder (AUD). The agitation in Alzheimer’s disease program is Phase 2 ready with FDA Fast Track designation and the development for AUD is in the pre-Investigational New Drug (IND) application stage. TNX-601 CR (tianeptine oxalate controlled-release tablets) is in development as a daytime treatment for PTSD, as well as for depression. The first efficacy study will be performed outside the U.S. and it is expected to be IND-ready in 2020. TNX-1600 (a triple reuptake inhibitor) is a third product candidate being developed for PTSD, as a daytime treatment. Tonix‘s programs for treating addiction conditions also include TNX-1300*** (double-mutant cocaine esterase), which is in Phase 2 development for the treatment of cocaine intoxication and has FDA Breakthrough Therapy Designation. Tonix’s preclinical pipeline includes TNX-1500 (anti-CD154), a monoclonal antibody being developed to prevent and treat organ transplant rejection and autoimmune conditions, and TNX-1700 (rTFF2), a biologic being developed to treat gastric and pancreatic cancers. Finally, TNX-701 (undisclosed small molecule) to prevent radiation effects is being advanced as a medical countermeasure to improve biodefense.

*TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication.

**Tonmya has been conditionally accepted by the FDA as the proposed trade name for TNX-102 SL for the treatment of PTSD.

***TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution) is an investigational new biologic and has not been approved for any indication.

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 failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; 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, 2018, as filed with the Securities and Exchange Commission (the “SEC”) on March 18, 2019, and periodic reports on Form 10-Q filed with the SEC on or after the date thereof. Tonix does not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Contacts

Bradley Saenger (corporate)
Tonix Pharmaceuticals
investor.relations@tonixpharma.com
(212) 688-9421

Travis Kruse (media)
Russo Partners
travis.kruse@russopartnersllc.com
(212) 845-4272

Peter Vozzo (investors)
Westwicke
peter.vozzo@westwicke.com
(443) 213-0505

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