December 12, 2017

Tonix Pharmaceuticals Completes Positive Pre-IND Meeting with FDA for TNX-102 SL (Cyclobenzaprine HCl Sublingual Tablets) as a Clinical Candidate for Agitation in Alzheimer's Disease

FDA Official Minutes Support Tonix's Plan to File an IND in First Quarter 2018 for a Phase 2 Study

NEW YORK, Dec. 12, 2017 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), a company that is developing innovative pharmaceutical and biological products to address public health challenges and diseases with significant unmet needs, announced today that it recently held a pre-Investigational New Drug (IND) meeting with the U.S. Food and Drug Administration (FDA) to discuss its proposed development of TNX-102 SL*, the Company's patented sublingual tablet formulation of cyclobenzaprine hydrochloride (CBP) for bedtime use for the treatment of agitation in Alzheimer's disease (AAD). TNX-102 SL is currently in Phase 3 development for the treatment of posttraumatic stress disorder (PTSD).

Seth Lederman, M.D., President and Chief Executive Officer of Tonix, stated, "We are excited by our positive dialogue with FDA regarding the potential clinical utility of TNX-102 SL for agitation in Alzheimer's disease. Based on FDA's feedback, Tonix has the data needed to file an IND to support a potentially pivotal efficacy study. We plan to submit the TNX-102 SL IND for agitation in Alzheimer's disease in the first quarter of 2018."

Dr. Lederman continued, "We believe TNX-102 SL has the potential to treat agitation in Alzheimer's disease by improving sleep quality. It is anticipated that the development and approval of TNX-102 SL for agitation in Alzheimer's disease will benefit from the development program for PTSD. While initial NDA approval of TNX-102 SL for the treatment of PTSD, Tonmya®, remains our highest priority development program, we are also interested in exploring the clinical utility of TNX-102 SL in other indications and agitation in Alzheimer's disease is at the top of that list."

Dr. Gregory Sullivan, Chief Medical Officer of Tonix stated, "Agitation in dementia, dementia and moderate cognitive impairment are all associated with sleep disruption. The proposed sleep quality improvement mechanism of TNX-102 SL, coupled with its low dosage strength and bedtime dosing regimen makes it an ideal drug candidate to be investigated in agitation in Alzheimer's disease. The development of TNX-102 SL for agitation in Alzheimer's is part of our effort to investigate the proposed sleep quality improvement mechanism of TNX-102

SL in a number of established neuro-psychiatric disorders which are significant unmet needs."

*TNX-102 SL 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 (cyclobenzaprine HCl sublingual tablets) for PTSD.

About Agitation in Alzheimer's Disease

Agitation in Alzheimer's disease is associated with significant negative consequences for both patients as well as their caregivers. Development of agitation, or its worsening, is one of the most common reasons for patients having to transition to nursing homes and other long-term care settings. Currently, there is no FDA approved treatment for behavioral symptoms such as agitation and aggression which affects the quality of life of both the patients and caregivers[1]. Sleep disturbances and agitation are common and co-morbid features of Alzheimer's disease.[2] Currently there is widespread off-label use of atypical anti-psychotic medications for behavioral symptoms in Alzheimer's disease, despite the lack of evidence for their effectiveness and significant risks associated with their use in this population.[3] Behavioral symptoms are a major clinical complication of Alzheimer's disease. They are estimated to be present in as many as 50 percent of community-dwelling patients, and as many as 80 percent of nursing home residents. Agitation, which includes emotional lability, restlessness, irritability, and aggression, is one of the most distressing and debilitating of these behavioral complications of Alzheimer's disease. Agitation is likely to affect more than half of the 5.3 million Americans who currently suffer from Alzheimer's disease, and this number is expected to nearly triple by 2050.[1] The presence of agitation nearly doubles the cost of caring for patients with Alzheimer's disease, and agitation is estimated to account for more than 12 percent of the $256 billion in healthcare and societal cost of associated with Alzheimer's disease for the year 2017 in the United States.[1]

[1]The Alzheimer's Association, 2017 Alzheimer's Disease Facts and Figures: https://www.alz.org/facts/
[2]Rose, K. et al. (2015). *American Journal of Alzheimer's Disease & Other Dementias*, 30:78
[3]Greenblatt, H. K., & Greenblatt, D. J. (2016). *The Journal of Clinical Pharmacology*, 56:1048

About TNX-102 SL

TNX-102 SL is a patented sublingual tablet formulation of cyclobenzaprine hydrochloride which provides rapid transmucosal absorption and reduced production of a long half-life active metabolite, norcyclobenzaprine, due to bypass of first-pass hepatic metabolism. The U.S. Patent and Trademark Office has issued a patent (U.S. Patent No. 9,636,408) protecting the composition and manufacture of the unique Tonmya formulation. The Protectic™ protective eutectic and Angstro-Technology™ formulation claimed in the patent are important elements of Tonix's proprietary Tonmya composition. This patent is expected to provide Tonmya, upon NDA approval, with U.S. market exclusivity until 2034.

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing innovative pharmaceutical and biological products to address major

public health challenges and diseases with significant unmet needs. Tonix's lead product candidate, Tonmya, is in Phase 3 development as a bedtime treatment for PTSD. TNX-601 (tianeptine oxalate) is in the pre-IND application stage, also for the treatment of PTSD but designed for daytime dosing. Tonix is also developing TNX-801, a potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus, currently in the pre-IND application stage.

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, substantial competition; 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 risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. 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, 2016, as filed with the Securities and Exchange Commission (the "SEC") on April 13, 2017, 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 hereof.

Contacts

Jessica Morris (investors)
Tonix Pharmaceuticals
investor.relations@tonixpharma.com
(212) 980-9159

Rich Allan (media)
Russo Partners
rich.allan@russopartnersllc.com
(646) 942-5588

Source: Tonix Pharmaceuticals Holding Corp.