March 7, 2019

Tonix Pharmaceuticals Announces New European Use Patent for TNX-601

Patent Expected to Provide Intellectual Property Protection until 2029 for Use of TNX-601 (Tianeptine Oxalate) for the Treatment of Neurocognitive Dysfunction Associated with Corticosteroids

NEW YORK, March 07, 2019 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company) a clinical-stage biopharmaceutical company focused on developing pharmaceutical products to treat serious neuropsychiatric conditions and biological products to improve biodefense, today announced that the European Patent Office (EPO) issued European Patent No. 3246031 to the Company on February 27, 2019. The patent, "Method for Treating Neurodegenerative Dysfunction," claims the use of TNX-601, or tianeptine oxalate and other salts, for treating neurocognitive dysfunction associated with corticosteroid treatment. The patent is expected to provide market exclusivity until April 2029. Patents claiming the use of TNX-601, its structural analogs, and salts have previously been issued in the U.S., Canada and Europe.

"The grant of this European method of use patent is another step in expanding the patent portfolio for TNX-601," commented Seth Lederman, M.D., president and chief executive officer of Tonix. "Tianeptine oxalate, or TNX-601, is an important product in our pipeline and is being developed not only for steroid-induced neurocognitive impairment, but also as a daytime treatment for posttraumatic stress disorder. We are conducting a non-IND human pharmacokinetic study of a proprietary tianeptine oxalate formulation and expect to have data in the second half of this year."

Dr. Gregory Sullivan, Chief Medical Officer of Tonix added, "Side effects from corticosteroid use include impaired ability to concentrate, unclear thinking, sedation, and mental fatigue. We believe tianeptine aids in improving cognition in steroid-treated patients."

About TNX-601
TNX-601 is a novel oral formulation of tianeptine designed for daytime dosing at the pre-IND (Investigational New Drug) stage of development. Tonix discovered a novel salt and polymorph of tianeptine that may provide improved stability, consistency, and manufacturability as compared to known forms of tianeptine. Currently there is no tianeptine-containing product approved in the U.S., though tianeptine sodium (amorphous) has been available in Europe, Asia, and Latin America for the treatment of depression since 1987. Tianeptine modulates the glutamatergic system indirectly and reverses the neuroplastic changes that are observed during periods of stress and corticosteroid use. Tianeptine is a weak mu-opioid receptor (MOR) agonist, but does not have significant affinity for other known neurotransmitter receptors. Tianeptine sodium has an established safety profile from decades of use as an antidepressant in Europe, Asia, and Latin America. Several published

studies support the potential of tianeptine as a treatment for PTSD. TNX-601 is being developed under Section 505(b)(1) of the Federal Food, Drug and Cosmetic Act (FDCA) as a potential treatment for PTSD and neurocognitive dysfunction associated with corticosteroid use.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering and developing pharmaceutical products to treat serious neuropsychiatric conditions and biological products to improve biodefense through potential medical counter-measures. Tonix's lead program is for the development of Tonmya®*, which is in Phase 3 development as a bedtime treatment for PTSD. Tonix is also developing TNX-102 SL as a bedtime treatment for agitation in Alzheimer's disease under a separate IND to support a Phase 2, potential pivotal, efficacy study and has been designated a Fast Track development program by the FDA for this indication. TNX-601 (tianeptine oxalate) is in the pre-IND application stage, also for the treatment of PTSD but is believed to work by a different mechanism from TNX-102 SL and is designed for daytime dosing in addition to neurocognitive dysfunction associated with corticosteroid use. Phase 1 clinical study of TNX-601 in healthy volunteers will be conducted outside of the U.S. in 2019. Tonix's lead biologic candidate, TNX-801, is a potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus, currently in the pre-IND application stage.

**Tonmya has been conditionally accepted by the U.S. Food and Drug Administration (FDA) as the proposed trade name for TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for the treatment of PTSD. TNX-102 SL is an investigational new drug 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; 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, 2017, as filed with the Securities and Exchange Commission (the "SEC") on March 9, 2018, 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.

Contacts

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

Scott Stachowiak (media)
Russo Partners
scott.stachowiak@russopartnersllc.com
(646) 942-5630

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

Source: Tonix Pharmaceuticals Holding Corp.