October 7, 2019

Tonix Pharmaceuticals Announces that the European Patent Office Opposition Division Has Upheld Its Patent for the Use of the Active Ingredient in TNX-102 SL, Cyclobenzaprine, for the Treatment of PTSD

Patent Expected to Provide Intellectual Property Protection until 2030 for Use of Cyclobenzaprine in the Treatment of PTSD

NEW YORK, Oct. 07, 2019 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced that the European Patent Office's (EPO) Opposition Division has upheld the Company's European Patent 2501234B1 with claims covering compositions containing the active ingredient in TNX-102 SL, cyclobenzaprine, for use in treating the development, initiation, consolidation, and perpetuation of posttraumatic stress disorder (PTSD) symptoms following a traumatic event. This patent was originally granted by the EPO in September 2017 and an opposition was filed against the patent in June 2018.

The U.S. counterpart to the European patent is U.S. Patent No. 9,918,948, the validity of which is not being challenged. In addition to these patents, Tonix owns patents covering TNX-102 SL and its use to treat PTSD in the U.S., Europe, and other countries. Together, these patents protect the use of TNX-102 SL in Europe and elsewhere.

Tonix's President and Chief Executive Officer, Seth Lederman, M.D. said, "We believe that the outcome of the European opposition proceedings adds strength to the overall patent estate for TNX-102 SL. Tonix will continue to diligently defend the validity of its intellectual property portfolio."

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, to improve biodefense through potential medical counter-measures, to treat transplant rejection and to treat gastric and pancreatic cancers. Tonix's lead program is for the development of Tonmya* (TNX-102 SL), which is in Phase 3 development as a bedtime treatment for PTSD. Tonix is also developing TNX-102 SL as a bedtime treatment for fibromyalgia, agitation in Alzheimer's disease and alcohol use disorder, under separate Investigational New Drug

applications (INDs) to support potential pivotal efficacy studies. The fibromyalgia program is in Phase 3 development, the agitation in Alzheimer's program is Phase 2 ready and the alcohol use disorder program is in the pre-IND application stage. TNX-1300** (double-mutant cocaine esterase) is being developed under an IND and is in Phase 2 development for the treatment of life-threatening cocaine intoxication. Tonix has two other programs in the pre-IND application stage of development for PTSD, but with different mechanisms than TNX-102 SL and designed for daytime dosing: TNX-601 (tianeptine oxalate) and TNX-1600***, a triple reuptake inhibitor. TNX-601 is also in development for a potential indication - neurocognitive dysfunction associated with corticosteroid use. Data on TNX-601 from a Phase 1 clinical formulation selection pharmacokinetic study that is being conducted outside of the U.S. is expected in the second half of 2019. TNX-801 (live virus vaccine for percutaneous [scarification] administration) is a potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus, currently in the pre-IND application stage. TNX-1500 is being developed to prevent and treat organ transplant rejection, as well as to treat autoimmune conditions, and is in the pre-IND application stage. Finally, TNX-1700 is being developed to treat gastric and pancreatic cancers and is 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 for the treatment of PTSD. TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication.*

***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.*

****TNX-1600* ((2*S*,4*R*,5*R*)-5-(((2-aminobenzo[*d*]thiazol-6-yl)methyl)amino)-2-(bis(4-fluorophenyl)methyl)tetrahydro-2*H*-pyran-4-ol) is an inhibitor of reuptake of three monoamine neurotransmitters (serotonin, norepinephrine and dopamine), or a "triple reuptake" inhibitor.

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, 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

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
peter.vozzo@westwicke.com
(443) 213-0505

Source: Tonix Pharmaceuticals Holding Corp.