May 27, 2026

Tonix Pharmaceuticals Announces Publication of Phase 1 Clinical Data of TNX-1500, an Fc-Modified anti-CD40L (CD154) Monoclonal Antibody, in the Peer-Reviewed Journal of Clinical Immunology

Phase 1 data support TNX-1500 as a potentially first-in-class, best-in-class, third-generation anti-CD40L monoclonal antibody for the prevention of kidney transplant rejection

Phase 2 investigator-initiated study in adult kidney transplant at Massachusetts General Hospital (MGH) expected to initiate in the 2nd half of 2026 pending U.S. Food and Drug Administration (FDA) clearance of MGH's Investigational New Drug (IND) application

BERKELEY HEIGHTS, N.J., May 27, 2026 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) ("Tonix" or the "Company"), a fully integrated, commercial-stage biotechnology company, today announced the publication of a paper, "First-in-Human, Phase 1, Randomized, Double-Blind, Placebo-Controlled Study of TNX-1500, an Fc-Modified anti-CD154 Monoclonal Antibody, Evaluating the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Single-Ascending Doses in Healthy Adults," in the peer-reviewed *Journal of Clinical Immunology*. TNX-1500 is an investigational, third-generation Fc-modified IgG4 anti-CD40L (also known as CD154) monoclonal antibody (mAb) in development for the prevention of organ transplant rejection and the treatment of autoimmune diseases. The manuscript can be accessed at https://pubmed.ncbi.nlm.nih.gov/42053701/.

"The CD40L is a validated target for preventing organ rejection in transplant and treating autoimmune disease, yet no anti-CD40L mAb has been approved for any indication," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "TNX-1500 is a Phase 2 ready humanized mAb engineered to improve safety and tolerability relative to first-generation anti-CD40L mAbs, while preserving the durable half-life and certain effector functions associated with the Fc or crystallizable fragment. We believe the Phase 1 results show that these design objectives were achieved in TNX-1500."

Dr. Gregory Sullivan, M.D., Chief Medical Officer of Tonix Pharmaceuticals added, "The Phase 1 study evaluated TNX-1500's safety, tolerability, pharmacokinetics, and pharmacodynamics. TNX-1500 was generally well tolerated, demonstrated a favorable safety profile, suppressed the primary and secondary T cell-dependent antibody responses (TDARs) to keyhole limpet hemocyanin (KLH) antigen, and showed a half-life which supports monthly intravenous dosing. We expect a Phase 2, investigator-initiated study of TNX-1500

in the prevention of kidney allograft rejection at MGH to begin in the 2nd half of 2026 pending clearance of the IND by the FDA."

The publication reports findings from a single-center, first-in-human, Phase 1, randomized, double-blind, placebo-controlled, single-ascending dose escalation study in 26 healthy adult volunteers. Participants were enrolled across three ascending dose cohorts (3, 10, and 30 mg/kg) or placebo and received a single intravenous infusion of TNX-1500 or placebo, followed by intramuscular injections of KLH on days 2 and 29 to assess the TDAR, and monitored over a 120-day follow-up period. TNX-1500 blocked the primary T cell–dependent antibody response to KLH at all doses, blocked the secondary response at the 10 and 30 mg/kg doses, and reduced peak secondary response to KLH by ~70% relative to placebo at the 3 mg/kg dose.

TNX-1500 was generally well tolerated, with no serious adverse events, and no discontinuations due to adverse events. The only treatment-emergent adverse event (TEAE) deemed possibly related to study drug was aphthous ulcer, which occurred in 1 participant in each of the three TNX-1500 groups; all TEAEs were rated as mild and resolved in 2-10 days. No TEAEs were determined to be related to KLH administration. There were no administration or injection site reactions (one of the prespecified TEAEs of special interest). Pharmacokinetic analyses suggested approximately dose-proportional exposure across the 3 to 30 mg/kg range, with mean terminal elimination half-lives of 37.8 and 33.8 days at the 10 and 30 mg/kg dose levels, respectively. TNX-1500 at 10 and 30 mg/kg blocked the primary and secondary anti-KLH TDAR through day 120, and at 3 mg/kg reduced the peak secondary response by approximately 70% relative to placebo. Across all dose cohorts, TNX-1500 was associated with a rapid (less than one-hour post-dose) and sustained reduction in soluble CD40L (sCD154) over the 120-day study period.

About TNX-1500

TNX-1500 (Fc-modified humanized anti-CD40L mAb) is a Phase 2 ready, humanized monoclonal antibody that interacts with the CD40-ligand (CD40L), also known as CD154. TNX-1500 is being developed for the prevention of kidney transplant rejection and the treatment of autoimmune diseases. Anti-CD40L has multiple potential indications in addition to solid organ and bone marrow transplantation including autoimmune diseases. Collaborations are ongoing with MGH on allo-heart and -kidney transplantation in nonhuman primates, as well as prevention of xenograft rejection, preclinical studies, and prevention of allograft rejection in sensitized patients. The Phase 2 investigator-initiated study by MGH is expected to initiate enrollment in the 2nd half of 2026, pending FDA clearance of the IND, to evaluate TNX-1500 in five kidney transplant recipients. The study is designed to assess the safety, tolerability, and activity of TNX-1500 in preventing kidney transplant rejection while decreasing the exposure to conventional immunosuppressive drugs, which are associated with infection, cancer, cardiovascular side effects, and various metabolic derangements with long term use.

Tonix Pharmaceuticals Holding Corp.

Tonix Pharmaceuticals* is a fully integrated, commercial-stage biotechnology company focused on central nervous system (CNS) disorders, infectious diseases, immunology conditions, and rare diseases where there exists high unmet medical need. TONMYA®

(cyclobenzaprine HCl sublingual tablets 2.8mg), the Company's flagship internally conceived and developed medicine, is the first new treatment for fibromyalgia in more than 15 years. Tonix's CNS commercial infrastructure supports its marketed products, including its acute migraine products, Zembrace® SymTouch® (sumatriptan injection 3 mg) and Tosymra® (sumatriptan nasal spray 10 mg). Tonix is extending the science behind TONMYA in Phase 2 clinical studies to evaluate its potential in major depressive disorder and acute stress disorder/acute stress reaction. Tonix is also advancing a pipeline of infectious disease programs, including monoclonal antibody TNX-4800 (anti-OspA mAb) for Lyme disease prevention in the U.S. and TNX-801 (horsepox, live virus vaccine), a vaccine in development for the prevention of mpox and smallpox. Within immunology, Tonix is developing TNX-1500 (anti-CD40L mAb), a third-generation CD40 ligand inhibitor for the prevention of kidney transplant rejection. Finally, the Company's rare disease portfolio includes TNX-2900, which is Phase 2 ready for the treatment of Prader-Willi syndrome. To learn more, visit www.tonixpharma.com.

**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.*

Forward Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995 including those relating to the completion of the offering, the satisfaction of customary closing conditions, the intended use of proceeds from the offering and other statements that are predictive in nature. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate," "expect," and "intend," among others. 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 successfully launch and commercialize TONMYA® and any of our approved products; risks related to the 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 in the Company's Annual Report on Form 10-K for the year ended December 31, 2025, as filed with the SEC on March 12, 2026, and periodic reports filed with the SEC on or after the date thereof. Tonix does not undertake an obligation to update or revise any forward-looking statement. 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.

Investor Contacts

Jessica Morris
Tonix Pharmaceuticals
(862) 799-8599
investor.relations@tonixpharma.com

Brian Korb
astr partners
(917) 653-5122
brian.korb@astrpartners.com

Media Contacts

Deborah Elson
Tonix Pharmaceuticals
deborah.elson@tonixpharma.com

Ray Jordan
Putnam Insights
ray@putnaminsights.com

Source: Tonix Pharmaceuticals Holding Corp.