September 10, 2024

Tonix Pharmaceuticals Announces Appointment of Thomas Englese as Executive Vice President of Commercial Operations

Thomas brings more than 20 years of commercial and operations experience in the biopharmaceutical industry to Tonix

Tonix is on track to submit an NDA for TNX-102 SL for fibromyalgia in October of 2024

CHATHAM, N.J., Sept. 10, 2024 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a biopharmaceutical company with marketed products and a pipeline of development candidates, today announced the appointment of Thomas (Tom) Englese as Executive Vice President of Commercial Operations, effective immediately. Mr. Englese brings significant leadership across several functions, including commercial operations, sales and marketing, and launching and managing major brands through all stages of commercialization.

“Tom brings extraordinary biopharmaceutical expertise as an industry leader with more than 20 years of commercial experience and a proven track record of launching and building commercial strategies and executing strategic growth planning,” said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. “We expect to submit the NDA for TNX-102 SL for fibromyalgia, a critical milestone for this program, in October of this year. Tom will be a valuable addition to Tonix as we advance the fibromyalgia program toward launch, and further build out our existing commercial and marketing capabilities.”

Mr. Englese offers breadth and depth of knowledge across numerous therapeutic areas and in different leadership positions. Prior to joining Tonix, he was the Chief Commercial Officer at Tris Pharmaceuticals, where he managed all commercial aspects of the company and was responsible for the re-branding, growth, and launch strategies for the ADHD business. Prior to Tris, Mr. Englese was Chief Commercial Officer at Aziyo Biologics where he set the strategic direction for the commercial organization for a diverse range of therapeutic businesses. Previously, Mr. Englese spent 11 years in various roles at Mallinckrodt PLC (formerly Ikaria Inc.), culminating in serving as the Senior Vice President and General Manager of North America Hospital Therapies. At Mallinckrodt, he was responsible for setting strategic direction and objectives to ensure alignment to corporate objectives for a +$1 billion North America franchise, and was accountable for the launch teams for several new products. Mr. Englese holds a Master of Business Administration in Finance from Pennsylvania State University and a Bachelor of Science in Marketing with a Minor in Communications from Villanova University. Mr. Englese succeeds the Company’s current

EVP, Commercial Operations, Jim Hunter, who is stepping down to pursue retirement.

“I am excited to join Tonix at this important point in the Company’s growth,” said Mr. Englese. “I look forward to working with the Tonix leadership team to advance TNX-102 SL and if approved, help bring it to patients who could benefit from its differentiated activity and profile.”

Tonix Pharmaceuticals Holding Corp.*

Tonix is a fully integrated biopharmaceutical company focused on transforming therapies for pain management and modernizing solutions for public health challenges. Tonix’s development portfolio is focused on central nervous system (CNS) disorders, and its priority is to submit a New Drug Application (NDA) to the FDA in October of 2024 for TNX-102 SL, a product candidate for which two statistically significant Phase 3 studies have been completed for the management of fibromyalgia. The FDA has granted Fast Track designation to TNX-102 SL for the management of fibromyalgia. TNX-102 SL is also being developed to treat acute stress reaction. Tonix’s CNS portfolio includes TNX-1300 (cocaine esterase), a biologic in Phase 2 development designed to treat cocaine intoxication that has Breakthrough Therapy designation. Tonix’s immunology development portfolio consists of biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is a humanized monoclonal antibody targeting CD40-ligand (CD40L or CD154) being developed for the prevention of allograft rejection and for the treatment of autoimmune diseases. Tonix also has product candidates in development in the areas of rare disease, including TNX-2900 for Prader-Willi syndrome, and infectious disease, including a vaccine for mpox, TNX-801. Tonix recently announced the U.S. Department of Defense (DoD), Defense Threat Reduction Agency (DTRA) awarded it a contract for up to $34 million over five years in an Other Transaction Agreement (OTA) to develop TNX-4200, small molecule broad-spectrum antiviral agents targeting CD45 for the prevention or treatment of infections to improve the medical readiness of military personnel in biological threat environments. Tonix owns and operates a state-of-the art infectious disease research facility in Frederick, MD, instrumental in progressing this development. Tonix Medicines, our commercial subsidiary, markets Zembrace® SymTouch® (sumatriptan injection) 3 mg and Tosymra® (sumatriptan nasal spray) 10 mg for the treatment of acute migraine with or without aura in adults.

*Tonix’s product development candidates are investigational new drugs or biologics and have not been approved for any indication.

Zembrace SymTouch and Tosymra are registered trademarks of Tonix Medicines.

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 the failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; risks related to the failure to successfully market any of our products; 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, 2023, as filed with the Securities and Exchange Commission (the "SEC") on April 1, 2024, 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.

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