March 20, 2024

Tonix Pharmaceuticals Announces Selection of Two Contract Manufacturing Organizations for the Launch and Commercial Manufacture of Tonmya™ for the Management of Fibromyalgia

Tonmya™ is a potential new first-line, centrally acting non-opioid analgesic for the management of fibromyalgia, supported by positive results from two Phase 3 studies

New Drug Application (NDA) submission to the FDA planned for second half of 2024

CHATHAM, N.J., March 20, 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 it has selected two contract manufacturing organizations (CMOs), one of which is Almac Pharma Services, a member of the privately owned Almac Group, as dual supply sources for the potential launch and commercialization of Tonmya™ (also known as TNX-102 SL, cyclobenzaprine HCl sublingual tablets) in the U.S.

“Dual sourcing is a critical element for the successful commercial launch and supply chain management of a product,” said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. “We are excited to advance our first internally developed program toward NDA submission and to work with two well-established CMOs for commercial supply and potential launch of Tonmya.”

“Having supported the development and clinical trial supply of this drug, we’re thrilled to be continuing our partnership with Tonix to support the commercial launch and ongoing supply of this important new non-opioid analgesic to patients with fibromyalgia, a chronic debilitating disease,” said Mark English, VP Operations, Almac Pharma Services.

Tonmya is a centrally acting, non-opioid medication. As previously announced, Tonix’s second positive Phase 3 study, RESILIENT, met its pre-specified primary endpoint, significantly reducing daily pain compared to placebo (p=0.00005) in participants with fibromyalgia. Statistically significant and clinically meaningful results (p=0.001 or better) were also seen in all key secondary endpoints related to improving sleep quality, reducing fatigue, and improving overall fibromyalgia symptoms and function. TNX-102 SL was well tolerated with an adverse event profile comparable to prior studies, and no new safety signals were observed.

Tonix plans to submit a New Drug Application (NDA) to the U.S. Food and Drug

Administration in the second half of 2024 for Tonmya for the management of fibromyalgia.

About Tonmya* (also known as TNX-102 SL)

TNX-102 SL is a tablet containing 2.8 mg cyclobenzaprine HCl that will be administered sublingually once daily at bedtime for the first 2 weeks, titrating subsequently to 2 tablets (5.6 mg total per day) at bedtime, as tolerated, for chronic, long-term use. The sublingual tablet is formulated using a patented Protectic™ eutectic formulation including a basifying agent for transmucosal absorption with rapid systemic exposure pharmacokinetic properties suitable for bedtime administration. The eutectic properties enhance the stability with a predicted shelf life of greater than 48 months, at room temperature conditions. The planned commercial distribution will be a 14, 60 and 90 count tablet bottles allowing for titration, flexible and three-month chronic supply. Tonmya is a centrally acting, non-opioid, non-addictive, bedtime medication. In December 2023, the Company announced highly statistically significant and clinically meaningful topline results in RESILIENT, a second positive Phase 3 clinical trial of Tonmya for the management of fibromyalgia. RELIEF, the first positive Phase 3 trial of Tonmya in fibromyalgia, was completed in December 2020. It met its pre-specified primary endpoint of daily pain reduction compared to placebo (p=0.010) and showed activity in key secondary endpoints.

*Tonmya™ is conditionally accepted by the U.S. Food and Drug Administration (FDA) as the tradename for TNX-102 SL for the management of fibromyalgia. Tonmya has not been approved for any indication.

About Almac Pharma Services

Tailormade pharmaceutical development and commercial solutions

With over 50 years' experience, Almac Pharma Services is a world leading outsourcing partner to the global pharmaceutical and biotechnology industry.

Employing over 1,600 highly skilled individuals across 4 locations in Europe and the US, the company provides tailored, quality-led and timely solutions from early and late phase pharmaceutical development, clinical and commercial drug product manufacture, product launch through to commercial packaging and global distribution.

On March 6, 2024, the company announced the completion of a custom-built, high-volume facility that significantly increases commercial manufacturing and packaging of sachet drug product presentations forming part of the Group's ongoing global expansion investment now totaling over £400 million.

To keep up to date with latest news, follow us onLinkedIn or visit our website.

About Almac Group

The Almac Group is an established contract development and manufacturing organisation providing an extensive range of integrated services across the drug development lifecycle to the pharmaceutical and biotech sectors globally. Its innovative services range from R&D, biomarker discovery development and commercialisation, API manufacture, analytical services, formulation development, clinical trial supply, IRT (IVRS/IWRS) through to commercial-scale manufacture.

The international company is a privately owned organisation which has grown organically, now employing 7,200 highly skilled personnel across 18 facilities including Europe, the USA and Asia.

To keep up to date with latest news, follow us onX and LinkedIn or visit almacgroup.com.

Tonix Pharmaceuticals Holding Corp.*

Tonix is a biopharmaceutical company focused on developing, licensing and commercializing therapeutics to treat and prevent human disease and alleviate suffering. Tonix's development portfolio is focused on central nervous system (CNS) disorders. Tonix's priority is to submit a New Drug Application (NDA) to the FDA in the second half of 2024 for Tonmya, a product candidate for which two positive Phase 3 studies have been completed for the management of fibromyalgia. TNX-102 SL is also being developed to treat acute stress reaction as well as fibromyalgia-type Long COVID. Tonix's CNS portfolio includes TNX-1300 (cocaine esterase) a biologic designed to treat cocaine intoxication with 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 and infectious disease. 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. All other marks are property of their respective owners.

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, 2022, as filed with the Securities and Exchange Commission (the "SEC") on March 13, 2023, 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.

Investor Contact

Jessica Morris
Tonix Pharmaceuticals
investor.relations@tonixpharma.com
(862) 904-8182

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

Media Contact

Ben Shannon
ICR Westwicke
ben.shannon@westwicke.com
443-213-0495

Source: Tonix Pharmaceuticals Holding Corp.