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FDA Recognizes Fibromyalgia as a 'Serious Condition' And Fast-Tracks New Drug Candidate

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CHATHAM, NJ / ACCESSWIRE / August 1, 2024 /When it comes to chronic pain conditions, fibromyalgia is among the most common, afflicting more than ten million people in the United States. Globally, 3-6% of the world's population suffers from this chronic disease that has no cure. While it is more prevalent in women, men and children across every race can also be afflicted with fibromyalgia.

With so many people suffering from a disease that brings widespread pain, fatigue and cognitive issues, it's no wonder the market for symptom treatment has seen steady growth over the years and is poised for more. By 2031, the fibromyalgia treatment market is projected to reach $3.86 billion growing at a CAGR of 3.3% between now and then.

Fibromyalgia is a Serious Disease

This form of chronic pain has become such a problem in the United States that the Food & Drug Administration (FDA) considers the disease to be a serious condition, which means it is a disease associated with morbidity that has a substantial impact on day-to-day functioning. After all, 70% of sufferers have difficulty with daily activities, 90% report poor sleep quality and 20% file disability claims.

Most treatments on the market today are a combination of medication and self-care focused on reducing symptoms and improving the quality of life. Unfortunately, due to dissatisfaction with the available treatment options, many patients (at the direction of their medical providers) turn to opioids to relieve their pain. As it stands, more people diagnosed with fibromyalgia are prescribed opioids than the bestselling FDA-approved drug duloxetine (generic Cymbalta). That's concerning, given opioids can be addictive and with time, life-threatening.

Of patients prescribed opioids for chronic pain, 21% to 29% misuse them while an average of 8% to 12% develop opioid use disorder. A U.S. policy to address opioid use, which killed more than 100,000 Americans in 2022, is aimed at curtailing imports of fentanyl and synthetics. Many experts believe a concurrent and perhaps more effective strategy is to provide pain sufferers relief with non-addictive products.

Fast Track Granted to TNX-102 SL*

The FDA has granted **Tonix Pharmaceuticals** (NASDAQ:TNXP) a fully integrated biopharmaceutical company Fast Track designation for TNX-102 SL (cyclobenzaprine HCl sublingual tablets), its drug candidate for the management of fibromyalgia. Tonix says the designation validates that fibromyalgia is a serious condition and that TNX-102 SL, which has no known addictive properties, has the potential to address this unmet medical need.

The FDA's Fast Track process is designed to facilitate development and expedite the review of therapies intended to treat serious conditions and address unmet medical needs to potentially get new treatments to patients sooner. Companies whose programs are granted Fast Track designation are eligible for more frequent interactions with the FDA during clinical development.

"The designation underscores the importance of addressing the unmet needs of fibromyalgia patients, who report dissatisfaction with current treatment options," said Seth Lederman, M.D., CEO of Tonix Pharmaceuticals. "If approved by the FDA, we expect TNX-102 SL to become the first new pharmacotherapy for fibromyalgia in over 15 years."

TNX-102 SL is a sublingual formulation of cyclobenzaprine hydrochloride designed to improve sleep quality rather than quantity, setting it apart from existing treatments, which fail to manage sleep disturbances that exacerbate fibromyalgia symptoms, the company says.

In recent Phase 3 trials, TNX-102 SL showed a statistically significant improvement in fibromyalgia pain with a p-value of 0.00005. Tonix reports that significant results were also seen in improving sleep quality, reducing fatigue and improving overall fibromyalgia symptoms and function. TNX-102 SL was well tolerated and the most common adverse events were transient sensations in the mouth corresponding with the disintegration of the tablet under the tongue.

New Drug Application Coming Soon

In addition to receiving Fast Track status, Tonix announced it is making progress on its new drug application (NDA), which it plans to submit to the FDA in the second half of this year. Coming out of pre-NDA meetings, Tonix said it is aligned with the FDA regarding the application for TNX-102 SL.

Tonix plans to request Priority Review designation for TNX-102 SL, and if granted, the FDA may accelerate the review of the new drug application.

"The NDA being prepared supports TNX-102 SL's potential position as a first-line non-addictive therapy for fibromyalgia, indicated for long-term daily use at bedtime," said Lederman.

*TNX-102 SL is an investigational new drug and has not been approved for any indication.

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