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Tonix's Experimental Non-Opioid Analgesic Treatment for Fibromyalgia Could Start Bringing Relief Later This Year

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Pain management is getting an upgrade, and Wall Street seems to be taking notice. For decades the pain drug market has been dominated by opioids that cause adverse side effects like addiction and overdose. In the wake of the opioid crisis and the new limitations on prescribing them, scientists and companies are chasing novel approaches to acute and chronic pain. A new crop of drugs is coming to the market to address acute and potentially chronic pain without many of the side effects, and that has Wall Street and pain sufferers paying close attention.

Vertex Sets the Stage

One only has to look at Vertex Pharmaceuticals, the drug company pursuing acute pain with a first-in-class NaV1.8 pain signal inhibitor drug. In January Vertex won Food and Drug Administration approval for VX-548, Journavx® (suzetrigine) its non-opioid drug for acute pain Suzetrigine. The company now sports a market capitalization of $123 billion, based also on it's other products. The trials that won approval for Journavx were in post-surgical settings after bunionectomy or tummy-tuck. These are indications in which short courses of opiates are generally prescribed and are recognized as useful.

Another company going after the pain market - albeit in a different area - with a non-opiate pain remedy for fibromyalgia is Tonix Pharmaceuticals Holding Corp. (NASDAQ:TNXP). Fibromyalgia is a chronic pain condition, not an acute pain condition. Fibromyalgia arises because of abnormal pain signaling in the brain, unlike acute pain, which is caused by tissue and nerve damage. The fully integrated biopharmaceutical company is developing its first-in-class tertiary amine tricyclic drug that acts in the central nervous system. Their drug TNX-102 SL* (cyclobenzaprine HCl sublingual tablets), a non-opioid investigational drug targeting fibromyalgia, which affects millions of Americans, mostly women.

This type of pain impacts a large portion of the body or can be specific to extremities like the feet or hands. Fibromyalgia inflicts pain over many parts of the body, which is called "widespread" or "multi-site" pain. In addition to living with the chronic widespread pain of fibromyalgia patients often complain of fatigue and sleep problems. Two other types of drugs are already approved to treat fibromyalgia, gabapentinoids like Pfizer's Lyrica® and SNRIs like Lilly's Cymbalta®. Despite the availability of these once-popular brands, many fibromyalgia patients are dissatisfied. Unlike acute pain, most experts agree that opioids should never be used to treat fibromyalgia. Most experts agree that opioids provide no meaningful benefit to fibromyalgia patients and only lead to addiction.

Tonix Positioning to Lead

Like Vertex in the acute pain market, Tonix is hard at work positioning itself to become a leader in treating the chronic pain of fibromyalgia with a non-addictive treatment that's in the final stages of seeking FDA approval.

It makes sense Tonix is going after the fibromyalgia market. Because fibromyalgia patients are typically affected for years or decades, and TNX-102 SL is expected to be used daily at bedtime, the number of prescriptions for each patient is expected to be larger than for acute pain which is typically a two-week course. However, both markets are large. According to one estimate the chronic pain drug market, which includes fibromyalgia, is forecast to grow from $72.10 billion in 2024 to over $115.51 billion by 2031, and the acute pain drug market is forecast to reach $103.6 billion by 2035.

Sleep disturbance can have a big impact on chronic pain, making it feel worse. Lack of sleep can also hyperexcite the central nervous system (CNS), lowering pain tolerance. TNX-102 SL is a sublingual formulation that is designed to be taken daily at bedtime and to target the disturbed sleep of fibromyalgia. TNX-102 SL is not believed to be a sedative or hypnotic like Ambien® or Lunesta®. These traditional sedatives fail to address the sleep problem of fibromyalgia. Ambien has been studied and it does not improve fibromyalgia symptoms.
FDA Approval Could Come as Soon as August

TNX 102-SL is currently being evaluated by the FDA and the company expects the FDA could issue a decision on marketing authorization on August 15, 2025. That means it could potentially be on the market in 2025, giving fibromyalgia sufferers a much-needed new option. As it stands, Tonix says 85% of fibromyalgia patients fail their first-line therapy and 79% are on multiple therapies to no avail.

Fibromyalgia can occur by itself, but it can also occur in the context of other conditions. The National Academies of Science, Engineering and Medicine (NASEM) recognized in June of last year that fibromyalgia is a diagnosable condition in Long COVID. The National Institute of Health just recently recognized that targeting sleep quality is a promising approach to treating long COVID. Tonix has completed a pilot study in multi-site pain associated with Long COVID and got encouraging results, particularly on improving fatigue.

The recommendation by the NASEM to diagnose fibromyalgia in appropriate Long COVID patients may expand Tonix's addressable market. After all, the number of long COVID sufferers, which according to the World Health Organization is about 6 in every 100 people who contract COVID, outnumbers those who are believed to suffer from fibromyalgia without Long COVID. New data from the Medical Expenditure Panel Survey support prior findings that around 7% of adults in the U.S. have long COVID, which amounts to 17.8 million adults. It's unknown how many of these people also have fibromyalgia.

From fibromyalgia to Long COVID patients and Wall Street, many are looking with hope at a new class of drugs to address an unmet need: pain medication that is not addictive and still effective. Companies like Vertex on the acute pain side and Tonix targeting fibromyalgia on the chronic pain side, are aiming to be leaders in these burgeoning markets. With Tonix's treatment under FDA review, it could be only a matter of time before that can potentially become a reality.

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

Click here for more information on Tonix Pharmaceuticals:

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Contact Information

Jessica Morris
Tonix Pharmaceuticals
investor.relations@tonixpharma.com
862.904.8182

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