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Tonix Pharmaceuticals Targets Rapid Migraine Relief With Non-Oral Treatments

This post was written and published as a collaboration between the in-house editorial team at Benzinga and Tonix Pharmaceuticals Holding Corp. with financial support from Tonix. The two organizations work to ensure that any and all information contained within is true and accurate as of the date hereof to the best of their knowledge and research. This content is for informational purposes only and not intended to be investing advice.

CHATHAM, NJ / ACCESSWIRE / November 14, 2024 For [millions](#) of people living with migraines, the pain can strike without warning, often during the most inconvenient times-like when they are fast asleep. The abrupt transition from sleep to a full-blown migraine leaves little room for preemptive action, especially when traditional oral migraine medications can take half an hour to an hour, or even more, to work.



But for those seeking immediate relief, **Tonix Pharmaceuticals** (NASDAQ:TNXP) is hoping to change the game. Through its subsidiary, Tonix Medicines, the biopharmaceutical company is marketing two products, [Zembrace® SymTouch®](#) (sumatriptan autoinjector) and [Tosymra® \(sumatriptan nasal spray\)](#), both promising potential migraine relief in as little as 10 minutes.

Tonix, known for its work in developing new treatments for central nervous system (CNS) conditions, acquired these migraine medications to cater to a growing need for faster, non-oral treatment options. For people who don't experience the early warning signs of migraines, such as auras, or for those who wake up already in the throes of pain, every minute matters. This is where Tonix's products could provide a critical edge.

Oral Medications: Slow To Absorb, Slow To Act

For most people, oral medications are the first line of defense against migraines. They are effective for many, but not without limitations. The problem lies in their delayed absorption into the bloodstream, which can be particularly problematic during a migraine attack. Gastroparesis, a condition where the stomach muscles slow down or stop digesting food, often [accompanies](#) migraines. This delayed digestion can make oral medications slower, or potentially ineffective because they are not absorbed quickly enough to provide relief.

Tonix's recent [awareness campaign](#), "Does Your Migraine Pill Work Every Time?" aims to address this issue head-on. Launched at the 2024 PAINWeek Conference, the campaign educates both migraine sufferers and healthcare providers on the importance of non-oral migraine treatments. Injectables and nasal sprays, which bypass the digestive system, may offer faster absorption and a quicker route to relief, the campaign argues.

"Non-oral migraine medications, such as injectables and nasal sprays, do not rely on the digestive system to be absorbed and can offer the potential for faster relief from migraine symptoms in as little as 10 minutes," said Dr. Deborah I. Friedman, a board-certified neuro-ophthalmologist and headache medicine specialist.

With this in mind, Friedman encourages healthcare providers to discuss non-oral treatment options with their patients, especially those who have not found success with traditional pills.

Zembrace SymTouch: Speed and Simplicity in a Single Dose

Tonix's Zembrace SymTouch could be a solution for patients who need migraine relief fast. This injectable formulation of sumatriptan, designed for acute migraine treatment, could provide relief in as little as 10 minutes for a portion of users, the company says. Company clinical trials found that [17%](#) of patients experience relief within this brief window, compared to just 5% with a placebo.

But Zembrace SymTouch isn't just fast, it can also be easy to use. The product comes in a small auto-injector that requires minimal preparation, making it convenient for migraine sufferers to carry and use on the go. The company says the injector features the smallest needle available among sumatriptan injectors, reducing discomfort for users. Additionally, it doesn't require refrigeration, which is a significant advantage for those who need to take their medication with them.

Tosymra: A Needle-Free, Fast-Acting Alternative

While some patients are comfortable with injections, others may prefer a needle-free option. This is where Tonix's Tosymra steps in. A nasal spray version of sumatriptan, Tosymra is designed to deliver the same rapid relief as Zembrace SymTouch but using Intravail® technology, which allows the medication to be absorbed directly through the nasal mucosa into the bloodstream, bypassing the gastrointestinal tract entirely. In the clinical studies, some patients experienced relief within 10 minutes after a single spray. By the two-hour mark, [57%](#) of patients reported significant pain reduction, compared to 21% who took a placebo.

The product's small, discreet design adds to its appeal. For migraine sufferers who need immediate relief without the hassle of needles or pills, Tosymra offers a portable, potentially fast-acting alternative that fits easily into a purse or pocket.

Expanding Beyond Migraines: Tonix's Strategic Moves

Tonix's focus on non-oral migraine treatments highlights an important potential shift in the way migraines are managed. Many people with migraines, especially those experiencing gastroparesis, struggle with oral medications because they are not absorbed fast enough during an attack. By offering two different non-oral solutions, Tonix hopes to fill a critical gap for people who need faster and more reliable relief.

Tonix's [acquisition](#) of Zembrace SymTouch and Tosymra from Upsher-Smith Laboratories was not just about improving options for migraine patients. The company says it was a strategic move to build out Tonix's commercial infrastructure ahead of the FDA submission of its New Drug Application for [TNX-102 SL](#), its candidate for fibromyalgia—a chronic pain condition that affects millions.

Fibromyalgia, like migraines, is a disorder that often leaves patients grappling with pain management. If approved by the FDA, TNX-102 SL could help to position Tonix as a leader in the broader field of pain management, the company says.

Navigating a Competitive Market

Tonix faces some stiff competition in the migraine market. In November, the company reported \$11.3 million in trailing year sales for its migraine products, a figure that pales in comparison to industry giants like **Pfizer Inc.'s** Nurtec, which recorded [\\$356 million](#) in sales during the same period. Meanwhile, **AbbVie Inc.'s** Ubrelvy and Qulipta posted combined sales of [\\$381 million](#).

Tonix's ability to capture more market share could depend on how well it can spread awareness about the benefits of its fast-acting, non-oral treatments.

[Click here](#) for more information on Tonix Pharmaceuticals:

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Indication and Usage

Zembrace® SymTouch® (sumatriptan succinate) injection (Zembrace) and Tosymra® (sumatriptan) nasal spray are prescription medicines used to treat acute migraine headaches with or without aura in adults who have been diagnosed with migraine.

Zembrace and Tosymra are not used to prevent migraines. It is not known if Zembrace or Tosymra are safe and effective in children under 18 years of age.

Important Safety Information

Zembrace and Tosymra can cause serious side effects, including heart attack and other heart problems, which may lead to death. Stop use and get emergency help if you have any signs of a heart attack:

- discomfort in the center of your chest that lasts for more than a few minutes or goes away and comes back
- severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
- pain or discomfort in your arms, back, neck, jaw or stomach
- shortness of breath with or without chest discomfort
- breaking out in a cold sweat
- nausea or vomiting
- feeling lightheaded

Zembrace and Tosymra are not for people with risk factors for heart disease (high blood pressure or cholesterol, smoking, overweight, diabetes, family history of heart disease) unless a heart exam shows no problem.

Do not use Zembrace or Tosymra if you have:

- history of heart problems
- narrowing of blood vessels to your legs, arms, stomach, or kidney (peripheral vascular disease)
- uncontrolled high blood pressure
- hemiplegic or basilar migraines. If you are not sure if you have these, ask your provider.
- had a stroke, transient ischemic attacks (TIAs), or problems with blood circulation
- severe liver problems
- taken any of the following medicines in the last 24 hours: almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, ergotamines, or dihydroergotamine. Ask your provider for a list of these medicines if you are not sure.
- are taking certain antidepressants, known as monoamine oxidase (MAO)-A inhibitors

or it has been 2 weeks or less since you stopped taking a MAO-A inhibitor. Ask your provider for a list of these medicines if you are not sure.

- an allergy to sumatriptan or any of the components of Zembrace or Tosymra

Tell your provider about all of your medical conditions and medicines you take, including vitamins and supplements.

Zembrace and Tosymra can cause dizziness, weakness, or drowsiness. If so, do not drive a car, use machinery, or do anything where you need to be alert.

Zembrace and Tosymra may cause serious side effects including:

- changes in color or sensation in your fingers and toes
- sudden or severe stomach pain, stomach pain after meals, weight loss, nausea or vomiting, constipation or diarrhea, bloody diarrhea, fever
- cramping and pain in your legs or hips; feeling of heaviness or tightness in your leg muscles; burning or aching pain in your feet or toes while resting; numbness, tingling, or weakness in your legs; cold feeling or color changes in one or both legs or feet
- increased blood pressure including a sudden severe increase even if you have no history of high blood pressure
- medication overuse headaches from using migraine medicine for 10 or more days each month. If your headaches get worse, call your provider.
- serotonin syndrome, a rare but serious problem that can happen in people using Zembrace or Tosymra, especially when used with anti-depressant medicines called SSRIs or SNRIs. Call your provider right away if you have: mental changes such as seeing things that are not there (hallucinations), agitation, or coma; fast heartbeat; changes in blood pressure; high body temperature; tight muscles; or trouble walking.
- hives (itchy bumps); swelling of your tongue, mouth, or throat
- seizures even in people who have never had seizures before

The most common side effects of Zembrace and Tosymra include pain and redness at injection site (Zembrace only); tingling or numbness in your fingers or toes; dizziness; warm, hot, burning feeling to your face (flushing); discomfort or stiffness in your neck; feeling weak, drowsy, or tired; application site (nasal) reactions (Tosymra only) and throat irritation (Tosymra only).

Tell your provider if you have any side effect that bothers you or does not go away. These are not all the possible side effects of Zembrace and Tosymra. For more information, ask your provider.

This is the most important information to know about Zembrace and Tosymra but is not comprehensive. For more information, talk to your provider and read the Patient Information and Instructions for Use. You can also visit <https://www.tonixpharma.com> or call 1-888-869-

7633.

You are encouraged to report adverse effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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