FDA Approves TREXIMET (sumatriptan and naproxen sodium) for Use in Pediatric Patients

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Approval marks the First Approved Combination and First Approved Sumatriptan Migraine Product for Patients Age 12-17

MORRISTOWN, NJ – May 15, 2015 – Pernix Therapeutics Holdings, Inc. (NASDAQ: PTX), a specialty pharmaceutical company, announced today that the U.S. Food and Drug Administration (FDA) has approved TREXIMET® (sumatriptan and naproxen sodium) for use in pediatric patients 12 years of age and older for the acute treatment of migraine with or without aura.[1]

TREXIMET is the first approved combination prescription medicine, and the first to contain sumatriptan, for the treatment of acute migraine attacks in pediatric patients.[1] The two medicines – sumatriptan and naproxen sodium – in combination provide more effective, sustained control of the pain and associated symptoms of migraine compared to either medicine taken alone.[2,3] Approval came after the FDA's review of pivotal phase 3 safety and efficacy clinical trial, plus long-term safety and pharmacokinetic data, demonstrating that TREXIMET is significantly more effective than placebo in treating migraine in pediatric patients and has a favorable safety profile similar to that of TREXIMET for adults.[4, 5, 6] TREXIMET carries a boxed warning noting cardiovascular and gastrointestinal risks. For full safety and efficacy information, please see the prescribing information. While TREXIMET has been approved for the acute treatment of migraine in adults since 2008, the FDA set a priority review of the supplemental New Drug Application based, in part, on the need for options among this specialty population. An estimated eight percent to 23 percent of all pediatric patients 11 years and older suffer from migraine[7], but treatment options have been limited, especially compared to adults.

"Until now, pediatric migraine sufferers have not had the same number of treatment options compared to adults to manage the potentially debilitating effects of acute migraine," said Merle Lea Diamond, M.D., president and managing director of the Diamond Headache Clinic and consultant to Pernix. "As many as one out of five teens suffers from migraines, and their burden goes well beyond the pain, as migraines can also adversely affect their social growth and their efforts in school."

"We are pleased with FDA's decision and look forward to bringing migraine relief to pediatric patients by making the new TREXIMET dose available in the third quarter of this year," said Doug Drysdale, Chairman and Chief Executive Officer of Pernix. "This expanded indication exemplifies our strategy to expand the reach of our current product portfolio to address additional underserved therapeutic areas, thereby adding value for patients and shareholders alike."

The recommended dose for pediatric patients 12 years of age and older is a single tablet of TREXIMET 10/60 mg (sumatriptan 10 mg and naproxen sodium 60 mg) per 24-hour period and the maximum recommended dose is 85/500 mg per 24-hour period.[1] The recommended dose for adults is a single tablet of TREXIMET 85/500 mg.[1]

About TREXIMET

TREXIMET was first approved by the U.S. Food and Drug Administration (FDA) in April 2008 for the acute treatment of migraine attacks, with or without aura, in adults. The product is formulated with POZEN's patented technology of combining a triptan with a non-steroidal anti-inflammatory drug (NSAID) and GlaxoSmithKline's (GSK) RT Technology™. TREXIMET has been shown to provide superior sustained pain relief compared to placebo and to both of the single mechanism of action components. In clinical trials, TREXIMET provided a significantly greater percentage of adult patients with migraine pain relief at two hours compared to sumatriptan 85 mg or naproxen sodium 500 mg alone. In addition, TREXIMET provided more patients sustained migraine pain relief from two to 24 hours compared to the individual components.

IMPORTANT SAFETY INFORMATION

Prescription TREXIMET is indicated for the acute treatment of migraine, with or without aura, in adults and in pediatric patients 12 years of age and older. The TREXIMET label includes a boxed warning noting cardiovascular and gastrointestinal risks. Carefully consider the potential benefits and risks of TREXIMET and other treatment options when deciding to use TREXIMET. TREXIMET is not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine (see CONTRAINDICATIONS). Safety and effectiveness of TREXIMET have not been established for cluster headache. TREXIMET should only be used where a clear diagnosis of migraine headache has been established. TREXIMET may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk. TREXIMET contains a non-steroidal anti-inflammatory drug (NSAID). NSAID-containing products cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events. TREXIMET is contraindicated in patients with history, symptoms, or signs of ischemic cardiac, cerebrovascular, or peripheral vascular syndromes and in patients with other significant underlying cardiovascular diseases. TREXIMET should not be given to patients in whom unrecognized coronary artery disease is predicted by the presence of risk factors without a prior cardiovascular evaluation. TREXIMET should not be given to patients with uncontrolled hypertension because the components have been shown to increase blood pressure. Concurrent administration of MAO-A inhibitors or use of TREXIMET within two weeks of discontinuation of MAO-A inhibitor therapy is contraindicated. TREXIMET and any ergotamine-containing or ergot-type medication (like dihydroergotamine and mthysergide) should not be used within 24 hours of each other. Since TREXIMET contains sumatriptan, it should not be administered with another 5-HT1 agonist. TREXIMET is contraindicated in patients with severe hepatic impairment. TREXIMET is contraindicated in patients who have had allergic reactions to products containing naproxen. It is also contraindicated in patients in whom aspirin or other NSAIDs/analgesic drugs induce the syndrome of asthma, rhinitis, and nasal polyps. Both types of reactions have the potential of being fatal. TREXIMET is contraindicated in patients with hypersensitivity to sumatriptan, naproxen, or any other component of the product. Cerebrovascular events have been reported in patients treated with sumatriptan. In a number of cases, it appears possible that the cerebrovascular events were primary. It is important to advise patients not to administer TREXIMET if a headache being experienced is atypical. The development of a potentially life-threatening serotonin syndrome may occur with triptans, including treatment with TREXIMET, particularly during combined use with selective serotonin reuptake inhibitors (SSRIs) or selective norepinephrine reuptake inhibitors (SNRIs). NSAID-containing products, including TREXIMET, should be prescribed with extreme caution in those with a prior history of ulcer disease or gastrointestinal bleeding. TREXIMET should not be used in late pregnancy because NSAID-containing products have been shown to cause premature closure of the ductus arteriosus. TREXIMET should not be used during early pregnancy unless the potential benefit justifies the potential risk to the fetus.

About Pernix Therapeutics

Pernix Therapeutics is a specialty pharmaceutical business with a focus on acquiring, developing and commercializing prescription drugs primarily for the U.S. market. The Company targets underserved therapeutic areas such as CNS, including neurology and pain management, and has an interest in expanding into additional specialty segments. The Company promotes its branded products to physicians through its two Pernix sales forces and markets its generic portfolio through its wholly owned subsidiaries, Macoven Pharmaceuticals, LLC and Cypress Pharmaceutical, Inc.

To learn more about Pernix Therapeutics, visit www.pernixtx.com.

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