Pernix Therapeutics Announces Distribution of TREXIMET® 10/60 mg (sumatriptan 10mg and naproxen sodium 60 mg) Dose For Use in Pediatric Patients

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Company to Begin Focused Product Promotion Activities in Early Q4 2016

MORRISTOWN, N.J., Sept. 28, 2016 (GLOBE NEWSWIRE) -- Pernix Therapeutics Holdings, Inc. (NASDAQ:PTX), a specialty pharmaceutical company with a focus on Pain and CNS conditions, today announced the distribution of TREXIMET® (sumatriptan and naproxen sodium) 10/60 mg to wholesalers has begun. TREXIMET 10/60 mg is indicated for use in pediatric patients 12 years of age and older for the acute treatment of migraine with or without aura.[1] TREXIMET received U.S. Food and Drug Administration (FDA) approval for use in the pediatric population 12 years of age and older in May 2015; however, this formulation just recently became available due to manufacturing delays. The Company expects to begin focused product promotion activities in early Q4 2016.

“We are pleased to make TREXIMET available for pediatric patients,” said John Sedor, Chairman and CEO of Pernix Therapeutics. “Pediatric migraine sufferers have long represented an underserved patient population,” continued Mr. Sedor. “TREXIMET has the potential to address a significant treatment void for pediatric patients.”

TREXIMET is the only approved combination prescription medicine containing sumatriptan and naproxen sodium for the treatment of acute migraine attacks in pediatric patients. In a study of 490 pediatric patients (ages 12-17), TREXIMET was well tolerated and more effective in providing pain freedom at 2 hours as compared to placebo.[1,2]

"There often remains a need for migraine treatment in adolescents. The availability of the FDA approved combination of sumatriptan-naproxen could prove to be very helpful for the pediatric population ages 12-17 with acute migraine with or without aura. The combination includes two powerful, proven anti-migraine medications with differing and complementary modes of action in a well-tolerated and safe single tablet for acute treatment of adolescent migraine," said Stewart Tepper, M.D., professor of neurology at the Geisel School of Medicine at Dartmouth.

Indication
Prescription TREXIMET® is used to treat acute migraine headaches with or without aura in patients 12 years of age and older.

TREXIMET® is not used to treat other types of headaches such as hemiplegic or basilar migraines. TREXIMET® is not used to prevent or decrease the number of migraine headaches you have. It is not known if TREXIMET® is safe and effective to treat cluster headaches.

Important Safety Information
TREXIMET® may increase your chance of a heart attack or stroke that can lead to death. Your chance of a heart attack or stroke increases with longer use of NSAID medicines or if you have heart disease or risk factors for heart disease.

Serious allergic or skin reactions, or stomach and intestine problems such as bleeding and ulcers, can occur without warning and may cause death. Risk of stomach and intestinal problems increases in the elderly.

Do not take TREXIMET® if you have heart problems, history of heart problems, or have ever had heart bypass surgery; had a stroke, TIAs, or problems with your blood circulation; hemiplegic migraines or basilar migraines; narrowing of blood vessels to your legs and arms, stomach, or kidneys; uncontrolled blood pressure; an allergy to aspirin, NSAIDs, sumatriptan or any of the ingredients in TREXIMET®; taken any medicines in the last 24 hours that are triptans or contain ergotamine; taken an MAOI antidepressant within the last 2 weeks; during third trimester of pregnancy; or liver problems. TREXIMET® should never be used if you have ever had a heart surgery called a coronary artery bypass graft (CABG).

Before you take TREXIMET®, tell your healthcare provider about all of your medical conditions including if you have risk factors for heart disease like high blood pressure, high cholesterol, diabetes, smoking, obesity, and heart problems or a family history of heart problems or stroke; kidney problems; liver problems; history of epilepsy or seizures; are pregnant, think you might be pregnant, or are trying to become pregnant; are breastfeeding or plan to breastfeed. Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Serotonin syndrome is a rare but serious problem that can happen in people using TREXIMET®, especially if used with antidepressants called SSRIs or SNRIs.

The most common side effects of TREXIMET® include: dizziness; feeling weak, drowsy, or tired; pain, discomfort, or stiffness in your neck, throat, jaw, or chest; nausea; tingling or numbness in your fingers or toes; heartburn; dry mouth; feeling hot; heartbeat problems; and muscle tightness.

For more information, please see the complete Prescribing Information, including BOXED WARNINGS, and the Medication Guide at www.treximet.com.

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

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.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Statements including words such as “estimate,” “plan,” “project,” “forecast,” “intend,” “expect,” “anticipate,” “believe,” “seek,” “target” or similar expressions are forward-looking statements. These statements reflect the Company’s current views, expectations and beliefs concerning future events. These forward-looking statements include statements regarding: planned development activities relating to a next-generation version of Zohydro ER, estimated annualized cost savings and potential for future revenue growth and profitability resulting from the restructuring of our salesforce and the recent management changes, increased usage of our three core products, Treximet, Silenor and Zohydro ER, increased usage of our prescription fulfillment program, Pernix Prescriptions Direct, and improved financial flexibility through a possible restructuring of our debt and other potential alternatives. The inclusion of forward-looking statements should not be regarded as a representation by Pernix that any of its plans will be achieved. Investors should note that many factors, including the risks and uncertainties inherent in Pernix’s business, as more fully described in Pernix’s filings with the U.S. Securities and Exchange Commission (SEC), including its Annual Report on Form 10-K for the year ended December 31, 2015 and subsequent filings with the SEC, could affect the Company’s future financial results and could cause actual results to differ materially from those expressed in forward-looking statements contained in this press release. The forward-looking statements in this press release are qualified by these risk factors. These are factors that, individually or in the aggregate, could cause our actual results to differ materially from expected and historical results. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company assumes no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

REFERENCES

1. TREXIMET Prescribing Information. Updated May 2016.
2. Derosier, FJ. Randomized Trial of Sumatriptan and Naproxen Sodium Combination in Adolescent Migraine.

Pediatrics 2012.

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