Pernix Therapeutics Overcomes Challenge to Treximet® ‘183 Patent

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MORRISTOWN, N.J., May 09, 2016 (GLOBE NEWSWIRE) -- Pernix Therapeutics Holdings, Inc. (NASDAQ:PTX), a specialty pharmaceutical company, today announced that on May 6, 2016, the Patent Trial and Appeal Board (PTAB) of the United States Patent and Trademark Office (USPTO) denied a petition for *inter partes* review (IPR) filed by Graybar Pharmaceuticals, LLC (now Gray Square Pharmaceuticals, LLC) against Pozen, Inc. This petition, which was filed on November 12, 2015, sought review of certain claims of U.S. Patent No. 7,332,183 (’183 patent), which expires 2026. The ‘183 patent is licensed by Pernix and is one of several FDA Orange Book listed patents covering Treximet®, manufactured and sold by Pernix Therapeutics, (sumatriptan/naproxen sodium), a prescription medication for acute migraine attacks, with or without aura.

The PTAB Ruled: “After considering the Petition and Preliminary Response, we determine that Petitioner has not established a reasonable likelihood of prevailing with respect to any of the challenged claims of the ’183 patent. *See* 35 U.S.C. § 314(a). Accordingly, we deny the Petition, and do not institute *inter partes* review.”

“We are pleased with the PTAB’s decision to deny Gray Square’s petition,” said Doug Drysdale, Chairman and CEO of Pernix. “We continue to be confident in the validity of the ’183 patent and the other FDA Orange Book listed patents covering Treximet as well as all of our brands.”

The ‘183 patent has resulted in the denial of at least three generic companies gaining market entry until 2026. The validity of the ‘183 patent has been previously up-held by the Federal Circuit and now the PTAB; further strengthening this patent and reinforcing limited generic entry beyond 2018 and until the ‘183 patent expires in 2026. As a result, Pernix expects to retain a meaningful market share with its own authorized generic version of Treximet, which it intends to launch via its Macoven subsidiary, in 2018.

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 Pernix sales force 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.

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.

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.

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