Pernix Therapeutics Announces Positive Phase IV Results of Silenor® vs. Zolpidem Head-to-Head Arousability Study

Data demonstrated that Pernix Therapeutics' Silenor® 6 mg was superior to zolpidem 10 mg on all measures evaluated.

Study results presented at SLEEP 2016 international meeting

MORRISTOWN, NJ – June 16, 2016 -- Pernix Therapeutics Holdings, Inc. (NASDAQ: PTX), a specialty pharmaceutical company, today announced positive final results from a Phase IV Study assessing the effects of nighttime administration of insomnia treatments, Silenor® 6 mg and zolpidem 10 mg, as well as placebo, on arousability, gait, balance, and cognitive performance, after going to sleep, in healthy male volunteers. These data were presented at the SLEEP 2016 International meeting, which took place on June 14th and 15th in Denver, Colorado.

The study assessed the effects of a single dose of Silenor 6 mg compared with matching placebo and a single dose of zolpidem 10 mg compared to its matching placebo at the respective Tmax (time the maximum serum concentrations are observed) in normal healthy adult male volunteers (n=52). The results of the study demonstrated that Silenor 6 mg was statistically superior to zolpidem 10 mg on the measures studied – arousability, gait, balance, and memory.

John Sedor, Chairman and CEO of Pernix Therapeutics, said, "The results of this head-to-head study further support certain key benefits of Silenor 6 mg. Pernix is encouraged by these data and the impact they could have on the sleep community and patients."

The results also indicated that subjects taking Silenor 6 mg did not have impairment on arousability, gait, balance, and cognitive performance, and were comparable to placebo. Further, in addition to Silenor 6 mg, both placebo groups were also statistically superior to zolpidem on the measures evaluated, indicating that zolpidem subjects had statistically significant difficulty in waking up, with walking and balance and with memory. Finally, there were no differences in efficacy measures between zolpidem 10 mg and Silenor 6 mg, while several measures were significantly improved with Silenor 6 mg versus placebo.

"One of the most interesting findings in the study was that a majority of the subjects in the zolpidem group did not wake up until they were exposed to noise of at least 110 decibels (dB; 64%)," stated Heith Durrence, Ph.D., Sleep Expert and Medical Director at Pernix Therapeutics. "The awakening threshold data indicate that subjects taking zolpidem could have difficulty waking up to noises similar to a jackhammer (average of 100 dB), a potentially serious issue."

About Pernix Therapeutics Holdings, Inc.

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.

About Silenor

SILENOR® is a prescription sleep medicine that is used to treat people with insomnia who have trouble staying asleep.

Important Safety Information about Silenor

Call your doctor if your insomnia worsens or is not better within 7 to 10 days. This may mean that there is another condition causing your sleep problem.

Be sure that you are able to devote 7 to 8 hours to sleep before being active again. SILENOR® should be taken within 30 minutes of bedtime. Do not take with alcohol or with other medicines that can make you sleepy. If you are on a monoamine oxidase inhibitor (MAOI) or have taken a MAOI within the past two weeks, you should not take SILENOR®. You should not take SILENOR® if you have an eye problem called narrow angle glaucoma that is not being treated, if you have severe urinary retention, or if you are allergic to any of the ingredients in SILENOR®. You should not drive or operate machinery at night after taking SILENOR®. Until you know how you will react to SILENOR®, you should be careful in performing such activities during the day following taking SILENOR®. Before you take SILENOR®, tell your doctor if you have a history of depression, mental illness or suicidal thoughts. You should call your doctor right away if after taking SILENOR® you walk, drive, eat or engage in other activities while asleep. Drowsiness is the most common adverse event observed in clinical trials. For more information, please see the complete Prescribing Information, including the Medication Guide.

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.

Silenor® is a registered trademark of Pernix Therapeutics Holdings, Inc.
To learn more about Silenor, visit www.silenor.com

Pernix Therapeutics Holdings, Inc.

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