Zogenix Reports Positive Development on U.S. District Court Ruling

July 9, 2014

Judge Upholds Prior Decision That State Regulations Cannot Usurp Federal Law

SAN DIEGO, July 9, 2014 (GLOBE NEWSWIRE) -- Zogenix, Inc. (Nasdaq:ZGNX) today commented on the order issued by the U.S. District Court in Massachusetts upholding its prior decision that imposing regulations to restrict access to Zohydro® ER (hydrocodone bitartrate) Extended-Release Capsules, CII, violates Constitutional law.

"This ruling upholds the important principle that a state cannot take action that could reverse the approval of a prescription drug product by the United States Food and Drug Administration (FDA). We are pleased that the emergency rules restricting patient access to Zohydro ER have been modified and clearly state than Zohydro ER can now be prescribed in accordance with its FDA-approved label," said Roger Hawley, chief executive officer of Zogenix. "However, we are closely evaluating the impact of the final regulations issued last week by Governor Patrick and the Board of Registration in Medicine and the Board of Registration in Pharmacy, to ensure pharmacy practices are equal for all extended-release opioids, including Zohydro ER, given the Federal District Court Judge Zobel's caution that regulations which would impede Zohydro ER's availability may 'pose significant constitutional concerns'."

The court's decision supports the importance of upholding the principle at the heart of this case, which is that the FDA is the only regulatory body that is authorized to determine the approval and access of medicines for all Americans. On October 25, 2013, the FDA approved Zohydro ER for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate, and today's decision preserves access for those in Massachusetts who may benefit from its medical attributes and sets a precedent for other states seeking to unjustly restrict access to Zohydro ER.

Zogenix will continue to work to ensure patients have access to Zohydro ER in every state in a manner that is consistent with all extended-release opioids.

About Zohydro® ER

INDICATION

ZOHYDRO® ER is an opioid agonist, extended-release, oral formulation of hydrocodone bitartrate indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

LIMITATIONS OF USE

Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve ZOHYDRO ER for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.

ZOHYDRO ER is not indicated for use as an as-needed analgesic.

Please click here to see the ZOHYDRO ER professional product labeling for the complete **boxed warning** and safety information.

WARNING: ADDICTION, ABUSE AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL EXPOSURE; NEONATAL OPIOID WITHDRAWAL SYNDROME and INTERACTION WITH ALCOHOL

- **ZOHYDRO ER exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk before prescribing, and monitor regularly for development of these behaviors or conditions.**
- **Serious, life-threatening, or fatal respiratory depression may occur. Monitor closely, especially upon initiation or following a dose increase. Instruct patients to swallow ZOHYDRO ER whole to avoid exposure to a potentially fatal dose of hydrocodone.**
- **Accidental consumption of ZOHYDRO ER, especially in children, can result in fatal overdose of hydrocodone.**
- **For patients who require opioid therapy while pregnant, be aware that infants may require treatment for neonatal opioid withdrawal syndrome. Prolonged use during pregnancy can result in life-threatening neonatal opioid withdrawal syndrome.**
- **Instruct patients not to consume alcohol or any products containing alcohol while taking ZOHYDRO ER because co-ingestion can result in fatal plasma hydrocodone levels.**

IMPORTANT SAFETY INFORMATION

ZOHYDRO ER is contraindicated in patients with: significant respiratory depression; acute or severe bronchial asthma or hypercarbia; known or suspected paralytic ileus; and hypersensitivity to hydrocodone bitartrate or any other ingredients in ZOHYDRO ER. ZOHYDRO ER contains hydrocodone, a Schedule II controlled substance. As an opioid, ZOHYDRO ER exposes users to the risks of addiction, abuse, and misuse. As modified-release products, such as ZOHYDRO ER, deliver the opioid over an extended period of time, there is a greater risk for overdose and death due to the larger amount of hydrocodone present. Potential serious adverse events caused by opioids include respiratory depression, potential for misuse and abuse, CNS depressant effects, prolonged gastric obstruction, and severe hypotension. The most common adverse reactions associated with ZOHYDRO ER (≥2%) include constipation, nausea, somnolence, fatigue, headache, dizziness, dry mouth, vomiting, pruritus, abdominal pain, peripheral edema, upper respiratory tract infection, muscle spasms, urinary tract infection, back pain and tremor.

For more information about Zohydro ER, please visit: www.ZohydroEr.com or the Zohydro ER REMS website at www.ZohydroERREMS.com.

About Zogenix

Zogenix, Inc. (Nasdaq:ZGNX) is a pharmaceutical company committed to developing and commercializing therapies that address specific clinical needs for people living with pain-related conditions and CNS disorders who need innovative treatment alternatives to help them return to normal daily functioning.

For more information about Zogenix, please visit: www.Zogenix.com.

Forward-Looking Statements

Zogenix cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "indicates," "will," "intends," "potential," "suggests," "assuming," "designed" and similar expressions are intended to identify forward-looking statements. These statements are based on the company's current beliefs and expectations. These forward-looking statements include statements regarding: access for patients to Zohydro ER in Massachusetts and other states. The inclusion of forward-looking statements should not be regarded as a representation by Zogenix that any of its plans will be achieved. Actual results may differ from those set forth in this press release due to the risk and uncertainties inherent in Zogenix's business, including, without limitation: Zogenix may be required to expend significant cash and other resources in connection with continuing litigation concerning access to Zohydro ER; the availability of Zohydro ER may suffer from negative publicity and political influences relating to the regulation of opioids as well as general public concern regarding the safety of opioids; Zogenix may be unable to achieve broad market acceptance and generate significant revenues from sales of Zohydro ER; competition from other pharmaceutical or biotechnology companies and other risks detailed in Zogenix's prior press releases as well as in public periodic filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Zogenix undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

Zohydro® ER is a registered mark of Zogenix, Inc.

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