Zogenix Announces Ruling Preventing the Implementation of Massachusetts Governor's Order that Blocked Access to Zohydro™ ER

April 15, 2014

SAN DIEGO, April 15, 2014 /PRNewswire/ -- Zogenix, Inc. (Nasdaq: ZGNX), a pharmaceutical company developing and commercializing products for the treatment of pain-related and central nervous system (CNS) disorders, today announced that the U.S. District Court in Massachusetts entered an order, preventing the implementation of the Commonwealth's ban of Zohydro™ ER on Constitutional grounds. This order will become effective on April 22, 2014.

The court decision today supports the importance of upholding the Constitutional principle at the heart of this case. The United States Food and Drug Administration (FDA) approved Zohydro™ ER (hydrocodone bitartrate) Extended-Release Capsules, CII, 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. This approval was based on a thorough review of the safety and effectiveness data in support of Zohydro ER. Allowing states to overturn the decisions of medical and scientific professionals at the FDA, which is the federal agency Congress has authorized to regulate matters involving patient safety and the effectiveness of medications, would set an alarming precedent with respect to the federal regulation of access to new prescription medications. After careful consideration, the District Court agreed.

"Today's legal ruling was a positive step forward for Massachusetts patients," stated Roger Hawley, chief executive officer of Zogenix. "We invite concerned officials to engage with us to discuss fair and appropriate safeguards for pain medications like Zohydro ER rather than seeking to ban or restrict one specific treatment."

Zogenix will continue to work to ensure patients suffering from severe chronic pain have access to the FDA approved medications they need in every state nationwide.

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 (prn) analgesic.

Please see the Zohydro ER full prescribing information 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.

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: the legality and appropriateness of the ban of Zohydro ER by executive order of the Governor of Massachusetts; and the potential to ensure physician and patient access to Zohydro ER in Massachusetts and elsewhere. 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 unsuccessful in the lawsuit seeking a temporary restraining order and may incur significant costs in connection with such lawsuit; 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 trademark of Zogenix, Inc.

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