

Zogenix Takes Legal Action in Federal Court to Block Massachusetts Improper Ban on Zohydro™ ER

Company Files for Injunction – Prescription Drug Status Should Reside Solely With the FDA

SAN DIEGO – April 7, 2014 – Zogenix, Inc. (Nasdaq: ZGNX), a pharmaceutical company developing and commercializing products for the treatment of pain-related and central nervous system (CNS) disorders, today filed a lawsuit in the U.S. District Court in Massachusetts requesting the court to grant a temporary restraining order against execution of the executive order recently announced by Governor Deval Patrick, which prohibits the prescribing and dispensing of the Company's prescription pain product that was approved by the U.S. Food and Drug Administration (FDA). Zohydro™ ER (hydrocodone bitartrate) extended-release capsules, is the first and only extended-release hydrocodone without acetaminophen 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.

The suit argues that this decision is in direct conflict with the authority of the FDA to determine on behalf of the public whether a drug is safe and effective, and to impose the measures necessary to ensure that the drug will be used safely and appropriately.

The legal action comes after a formal written request to the Governor for a meeting to discuss the facts about the product went unanswered. For those patients in Massachusetts struggling every day with severe chronic pain who are tolerating immediate-release hydrocodone therapies which contain acetaminophen, having a new option of hydrocodone could provide a significant benefit at the same daily dose currently being prescribed and taken 4 – 6 times per day and reduce their risk to overdose of acetaminophen.

“Governor Patrick’s unilateral action was taken without any communication or advanced notice. In very limited interactions with his staff after the decision, we are convinced the decision was driven by factual inaccuracies about the science and the data. Unfortunately, it left us little recourse but to put the needs of patients in severe chronic pain ahead of politics and file for an injunction to stop the executive order,” said Roger Hawley, chief executive officer of Zogenix. “Zohydro ER was approved by the FDA after an exhaustive 18-month review of the clinical trial data. This rigorous FDA review process serves the nation’s public health needs, the medical community and those in severe chronic pain, and the FDA regulatory authority simply should not be usurped by individual states.”

Zogenix Commitment to Ensuring Appropriate Use

Zogenix has taken extraordinary steps to ensure its medicine is used safely and prescribed according to the revised label required by the FDA for all extended release/long acting (ER/LA) opioid analgesics. In addition, Zogenix is also participating with the NDA sponsors of other ER/LA opioids in the design and conduct of post-marketing required studies to assess the potential for serious risks associated with long-term use of these medications.

Zohydro ER is the only hydrocodone product on the market today that is subject to a Risk Evaluation and Mitigation Strategy (REMS) specifically developed by the FDA to minimize the risk of abuse of long acting opioid drugs, and is the only hydrocodone product currently subject to Schedule II controls by the Drug Enforcement Administration. These requirements make Zohydro ER the most comprehensively regulated hydrocodone product on the market today, with more safeguards against misuse, abuse and diversion than any other hydrocodone-based product.

Extensive education is provided to patients and prescribers on the proper use of Zohydro ER by Zogenix to ensure they fully understand the risks associated with the use of extended release opioids. Zogenix has also implemented a broad and vigorous surveillance system under the oversight of an external safe use board to detect for signals of abuse, misuse and diversion in order to take immediate corrective actions, which began prior to the product becoming available on the market.

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 ($\geq 2\%$) 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. 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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