Zogenix Statement: Massachusetts Denies Patients a Legitimate Option for Severe Chronic Pain

March 28, 2014

SAN DIEGO, March 27, 2014 /PRNewswire/ -- We agree with Governor Deval Patrick's intention to curb the epidemic of drug abuse in Massachusetts. However, we are extremely concerned by his unprecedented action with respect to a specific FDA-approved prescription medication.

We believe Governor Patrick's ban on Zohydro™ ER only serves to unfairly restrict patient access to the only hydrocodone pain reliever available for long-term, daily, severe chronic pain patients who are obtaining relief with short-acting hydrocodone combination products, but who are at risk for potentially fatal liver toxicity due to their daily intake of acetaminophen. Ultimately, the ban on the prescription medication will add to patient suffering in the state.

Contrary to some recent media reports, most other opioid medications on the market today are both equal to or more potent than Zohydro ER (e.g., oxycodone, fentanyl, hydromorphone and oxymorphone), and all are available in higher strengths per unit-of-use than Zohydro ER. Claims that Zohydro ER is "more powerful" or "more addictive" than other commonly prescribed opioids are not supported by scientific data.

Over the last 12 months, more than 360,000 prescriptions for extended-release opioids were dispensed in Massachusetts, and a significant majority did not have FDA-approved abuse deterrent claims. We fail to see how banning the sale of a single new product will achieve the governor's policy objectives when all of the products that are currently part of the epidemic remain available for sale in the state. In fact, the U. S. Drug Enforcement Administration (DEA) assigns an allocation, or quota, for how much medicine manufacturers of opioids can make each year. It is important to know that the quota for Zohydro ER is less than one percent of the total allotted hydrocodone product that will be manufactured in the U.S. this year.

The simple fact is that any medication, including opioid pain relievers, presents a danger to the person misusing or abusing it. That's why Zogenix has taken extraordinary steps to support the appropriate use of Zohydro ER through a voluntary, comprehensive set of educational tools and safeguards to augment the FDA industry mandated class-wide Risk Evaluation Mitigation Strategy (REMS) for extended-release opioids. In an effort to provide additional safeguards against the potential diversion, overdose, and misuse of Zohydro ER, Zogenix has also established an External Safe Use Board of experts, and is compensating our product representatives not on sales volume of Zohydro ER, but rather on their efforts to ensure prescribers, pharmacists and patients are educated to understand the risks and benefits of using extended-release opioids. Finally, Zogenix provides patients who are prescribed Zohydro ER access to free locking pill bottle caps and discounted safe-storage units to prevent others in the home from obtaining easy access to medicine that was not prescribed for them.

We are disappointed that today legitimate severe chronic pain patients in Massachusetts received a serious blow in their efforts to find relief for the suffering that affects their – and their families'— daily lives.

We look forward to engaging with the governor and his representatives to review the safe use measures already in place.

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.

Zohydro ER uses Alkermes Pharma Ireland Limited's patented Spheroidal Oral Drug Absorption System (SODAS®) drug delivery technology, which serves to enhance the release profile of hydrocodone to provide extended-release pain relief relative to existing immediate-release combination products.

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), with offices in San Diego and Emeryville, California, is a pharmaceutical company committed to developing and commercializing therapies that address specific clinical needs for people living with pain-related conditions and central nervous system disorders who need innovative treatment alternatives to help them return to normal daily functioning. The Company has commercialized two products using technology to enhance the patient experience and has a development pipeline that includes a once-monthly subcutaneous injection for schizophrenia. More information about Zogenix is available at www.zogenix.com

Zohydro™ ER is a trademark of Zogenix, Inc.

SOURCE Zogenix, Inc.

Investors: Sherif El-Azzazi, The Ruth Group, 646.536.7032, selazzazi@theruthgroup.com Media: Victoria Fort, Chandler Chicco Companies, 202.361.0445, vfort@chandlerchiccocompanies.com