Zogenix Statement: Let's Get the Facts Straight About Zohydro ER

April 3, 2014

SAN DIEGO, April 2, 2014 /PRNewswire/ -- We are extremely disappointed that the U.S. Drug Enforcement Administration (DEA) Administrator, as she did in a Congressional hearing today, would repeat misinformation about Zohydro™ ER that has been demonstrated to be false.

As informed health care experts and the U.S. Food and Drug Administration have noted for the record, Zohydro ER is no more potent than any other hydrocodone medication available.

The facts are clear: Zohydro ER is the same hydrocodone currently available in a number of combination products, but without acetaminophen. In fact, in terms of hydrocodone potency, a 10 mg dose of Zohydro ER is actually the exact same potency as a 10 mg dose of Vicodin or any other hydrocodone product. There are also many marketed opioids that are more potent than hydrocodone such as oxymorphone, methadone, hydromorphone and fentanyl.

In terms of maximum strength in a single pill, all other extended-release opioids have a higher dosage strength than Zohydro ER. For example, the highest dosage unit of extended-release oxycodone is 80 mg and the highest dosage unit of extended-release morphine is 200 mg, both of which are substantially higher than the highest dosage unit of Zohydro ER (which ranges from 10 mg to 50 mg).

Zohydro ER is the only acetaminophen-free 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.

Like our nation's leaders, we are committed to the safe and appropriate use of prescription medications. 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.

As part of our continued efforts to provide additional safeguards against the potential diversion, overdose and misuse of Zohydro ER, Zogenix has established an External Safe Use Board of experts. Zogenix is also 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.

On behalf of those who suffer with severe chronic pain, we will continue to move aggressively to correct false and misleading statements about Zohydro ER. The plight of people living with severe chronic pain is too important to treat otherwise.

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.

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