FDA, HHS Reaffirm Support for Chronic Pain Patients Amid Zohydro ER Debate

April 4, 2014

SAN DIEGO, April 4, 2014 /PRNewswire/ -- Today, Health and Human Services (HHS) Secretary Kathleen Sebelius, and U.S. Food and Drug Administration (FDA) Commissioner Dr. Margaret Hamburg, called for a balanced approach in the fight against prescription drug abuse and preserving the protection of the needs and rights of patients suffering from severe chronic pain. It was an impressive showcase of a unified front and a call for all stakeholders to help at every level.

It is vitally important for the health and safety of all Americans that our expert professional regulators and health care officials in federal and state agencies are allowed to do their jobs without political interference from politicians who have neither medical nor scientific training. Commissioner Hamburg has made a sensible case that fighting prescription drug abuse in America requires a comprehensive and coordinated approach without affecting access to opioid medications, which can have a dramatic positive effect on the lives of patients suffering from severe debilitating chronic pain.

We agree with Commissioner Hamburg's call for preserving access to pain medicines for the patients who need them the most. We believe that allowing politicians who have incomplete and false information to force a reversal of the FDA's considered decision to approve Zohydro™ ER – or any other medication – after that agency's painstaking review, would set a very dangerous precedent.

The announcement by Vermont today is a case in point. While we appreciate the fact that Vermont authorities have not completely shut the door on chronic pain patients in their state with regard to access to Zohydro ER, we have serious concerns that they have added additional restrictions to only one specific product. Because there are risks of misuse and abuse to all opioid medications, we believe that any restrictions should be applied to all Schedule II opioids, including both extended release and immediate release opioid medications. These actions in Vermont and other states that have voiced opposition to Zohydro ER, fly in the face of sound regulatory and legislative guidance at the federal level and represent an arbitrary and short-sighted view of this complex issue.

To ensure we do our part to protect our communities, Zogenix is the first and only opioid pharmaceutical company which has implemented a number of voluntary and novel safeguards from the first day of availability of their product to minimize the potential diversion, overdose and misuse of Zohydro ER, including:

- Establishment of an External Safe Use Board of experts to monitor and review prescriptions and report any patterns of abuse to the FDA and other federal authorities.
- Bringing to the forefront the critical role of education by 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.
- Providing 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.

In the spirit of the FDA's call for balance in fighting drug abuse while meeting the needs of patients in severe chronic pain, we at Zogenix truly want to be a partner in improving both the management of patients suffering from severe chronic pain and the reduction of misuse and abuse of prescription drugs in our country. We invite any public official or organization that may want to discuss our product or would like to learn more about the facts, to contact us at 1-866-964-3649, or visit us online at www.zogenix.com.

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.

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