

Pfizer and Acura Announce FDA Approval of OxectaTM (Oxycodone HCl, USP) CII

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([BUSINESS WIRE](#))--Pfizer Inc. (NYSE: PFE) and Acura Pharmaceuticals Inc. (NASDAQ: ACUR) announce the marketing approval from the U.S. Food and Drug Administration (FDA) of OXECTATM (oxycodone HCl, USP) Tablets CII. OXECTA is indicated for the management of acute and chronic moderate to severe pain where the use of an opioid analgesic is appropriate.

OXECTA is the first immediate-release oxycodone HCl medicine that applies technology designed to discourage common methods of tampering associated with opioid abuse and misuse. This AVERSION[®] Technology is a unique composition of commonly used pharmaceutical ingredients. Pfizer is licensing the technology in OXECTA from Acura.

Opioid medications are an important treatment option for patients with moderate to severe pain who are not adequately managed by other pain treatments. However, abuse and misuse of opioids is a serious public health issue that is the focus of a number of recent United States government initiatives.

"We recognize our responsibility to physicians and patients and remain committed to appropriate access to pain treatment and developing medicines to potentially address this important public health and safety issue," said Olivier Brandicourt, Pfizer president and general manager, Primary Care. "OXECTA will further expand Pfizer's presence in pain management and complements our growing, robust portfolio of treatments and medicines in development for pain relief, one of our strategic, high-priority disease areas. We are pleased to bring OXECTA to patients and physicians with our partner Acura."

"We are excited to be partnered with Pfizer to bring OXECTA to patients who need opioids to manage their pain," said Robert Jones, interim president and chief executive officer of Acura Pharmaceuticals, Inc. "Acura is focused on developing technologies that are intended to potentially deter abuse and misuse."

Important Safety Information

OXECTA is contraindicated in patients with respiratory depression in unmonitored settings and in the absence of resuscitative equipment, in any patient who has or is suspected of having paralytic ileus, in patients with acute or severe bronchial asthma or hypercarbia, and in patients with known hypersensitivity to oxycodone, oxycodone salts, or any components of the product.

Respiratory depression is the primary risk of OXECTA. This is more common in elderly or debilitated patients, in those suffering from conditions such as COPD, severe asthma, or upper airway obstruction, or following large initial doses of opioids given to non-tolerant patients.

OXECTA contains oxycodone HCl, an opioid agonist and a Schedule II controlled substance. Such drugs are sought by drug abusers and people with addictions. OXECTA can be abused in a manner similar to other opioids and narcotics. This should be considered when prescribing or dispensing oxycodone HCl in situations where the physician or pharmacist is concerned about an increased risk of misuse or abuse. OXECTA may be abused by crushing, chewing, snorting or injecting the product. These practices pose a significant risk to the abuser that could result in overdose and death. OXECTA should not be given to anyone other than the individual for whom it was prescribed. Keep OXECTA in a locked cabinet, drawer or medicine safe so that it will not be stolen.

There is no evidence that OXECTA has a reduced abuse liability compared to immediate-release oxycodone.

Take each OXECTA tablet with enough water to ensure complete swallowing immediately after placing in the mouth, and OXECTA must be swallowed whole. As OXECTA is not amenable to crushing and dissolution, do not use OXECTA in nasogastric, gastric or other feeding tubes as it may cause obstruction of feeding tubes.

Patients who have not been receiving opioid analgesics should start on OXECTA in a dosing range of 5 to 15 mg every 4 to 6 hours as needed for pain. The dose should be titrated based upon the individual patient's response to their first dose of OXECTA. Patients with chronic pain may need to be dosed at the lowest dosage level that will achieve acceptable pain relief and tolerable adverse reactions, on an around-the-clock basis rather than on an as needed basis. When a patient no longer needs treatment with OXECTA after long-term use, it is important to gradually taper OXECTA over time to prevent withdrawal symptoms.

Patients taking OXECTA in combination with other medicines like sedatives, anesthetics or narcotics may have serious problems such as respiratory depression, low blood pressure, profound sedation, or coma. Do not drink alcoholic beverages or take any medicines containing alcohol while taking OXECTA.

Use OXECTA with caution in patients with head injuries or other conditions that increase pressure in the brain, shock with low blood volume, severe undiagnosed abdominal conditions, history of seizures, severe kidney or liver disease, gall bladder disease, Addison's disease, hypothyroidism, enlarged prostate or other illnesses that make urination difficult and elderly or debilitated patients. Do not use OXECTA in patients with intestinal obstruction especially paralytic ileus.

Patients taking OXECTA should use caution when driving a car, operating heavy machinery or doing similar, potentially dangerous tasks as OXECTA may impair abilities needed to drive or perform potentially dangerous activities.

The most common adverse reactions are nausea, constipation, vomiting, headache, itchiness, trouble sleeping, dizziness, loss of strength/energy, and sleepiness.

Keep OXECTA out of the reach of children. If a child accidentally takes OXECTA, seek emergency medical help immediately.

For additional information on the prescribing information for OXECTA, please call 1 (800) 776-3637.

Pfizer Inc.: Working Together for a Healthier World™

At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best-known consumer products. Every day, Pfizer colleagues work across developed and emerging markets to

advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as the world's leading biopharmaceutical company, we also collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us.

To learn more about our commitments, please visit us at www.pfizer.com.

About Acura Pharmaceuticals

Acura Pharmaceuticals, Inc. is a specialty pharmaceutical company engaged in research, development and commercialization of product candidates intended to potentially deter abuse and misuse utilizing its proprietary AVERSION® and IMPEDE® technologies.

Acura will receive a \$20 million milestone payment from Pfizer based on the approval of OXECTA.

Acura Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 (the "Act"). Acura Pharmaceuticals, Inc. disclaims any intent or obligation to update these forward-looking statements, and claim the protection of the Safe Harbor for forward-looking statements contained in the Act. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. Important factors that may cause actual results to differ materially from the forward-looking statements are discussed in the "Risk Factors" section and other sections of the Companies' -6-

Annual Reports on Form 10-K for the fiscal year ended December 31, 2010, and their Quarterly Reports on Form 10-Q for the quarter ended March 31, 2011, each of which is on file with the U.S. Securities and Exchange Commission.

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