# PRESS RELEASE



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FOR IMMEDIATE RELEASE

## **ACURA PHARMACEUTICALS RECEIVES \$20 MILLION MILESTONE PAYMENT**

FDA Approval of Oxecta<sup>TM</sup> Triggers Payment

**Palatine, IL, July 1, 2011**: Acura Pharmaceuticals, Inc. (NASDAQ: ACUR) announced today the receipt of a \$20 million milestone payment from Pfizer, Inc. triggered by the U.S. Food and Drug Administration's (FDA) approval of Pfizer's New Drug Application (NDA) for OXECTA Tablets CII. OXECTA utilizes Acura's AVERSION Technology designed to discourage common methods of tampering associated with opioid abuse and misuse. The FDA approved OXECTA on June 17, 2011.

Acura and Pfizer jointly developed OXECTA and OXECTA is to be commercialized by Pfizer in accordance with the AVERSION Technology license. Pfizer has licensed three additional AVERSION Technology products from Acura, including oxycodone HCl/acetaminophen tablets and hydrocodone bitartrate/acetaminophen tablets.

#### **About the Pfizer Agreement**

Pfizer has an exclusive license to Acura's AVERSION Technology for utilization in four opioid products as well as an option to license additional opioid products, for development and commercialization in the United States, Canada and Mexico. Acura is eligible to collect from Pfizer an additional \$3 million for Pfizer's achievement of certain non-U.S. regulatory milestones for OXECTA and up to \$23 million for Pfizer's achievement of certain regulatory milestones for each of the 3 other unapproved licensed products.

### **Important Safety Information Regarding OXECTA**

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 accidently takes OXECTA, seek emergency medical help immediately.

### About Acura Pharmaceuticals, Inc.

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.

### **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. When used in this press release, the words "estimate," "project," "anticipate," "expect," "intend," "believe," and similar

expressions are intended to identify forward-looking statements. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. The most significant of such factors include, but are not limited to, our ability, or the ability of other pharmaceutical companies, to whom we may license our technology and/or product candidates, to obtain necessary regulatory approvals and commercialize products utilizing our proprietary technologies, the ability of Oxecta and other products utilizing our Aversion and Impede Technologies to deter abuse and misuse of such products upon commercialization, the ability to avoid infringement of patents, trademarks and other proprietary rights of third parties, and the ability to fulfill the U.S. Food and Drug Administration's ("FDA") requirements for approving our product candidates for commercial manufacturing and distribution in the United States, including, without limitation, the adequacy of the results of the laboratory and clinical studies completed to date and the results of other laboratory and clinical studies, to support FDA approval of our product candidates, the adequacy of the development program for our product candidates, changes in regulatory requirements, adverse safety findings relating to our product candidates, the unpredictability of the duration and results of FDA review of filings made with the FDA relating to our product candidates, the risk that the FDA may not agree with our analysis of our clinical studies and may evaluate the results of these studies by different methods or conclude that the results of the studies are not statistically significant, clinically meaningful or that there were human errors in the conduct of the studies, the risk that further studies of our product candidates are not positive or otherwise do not support FDA approval or commercially viable product labeling, the uncertainties inherent in scientific research, drug development, clinical trials and the regulatory approval process, and our ability to collect milestone payments. Other important factors that may also affect future results include, but are not limited to: our ability to attract and retain highly skilled personnel; our ability to timely submit regulatory filings with the FDA; our ability to secure and protect our patents, trademarks and proprietary rights; litigation or regulatory action that could require us to pay significant damages or change the way we conduct our business; our ability to compete successfully against current and future competitors; our dependence on third-party suppliers of raw materials; our ability to secure U.S. Drug Enforcement Administration quotas and source the active ingredients of our products in development; difficulties or delays in clinical trials for our product candidate or in the commercial manufacture and supply of our products; and other risks and uncertainties detailed in our Form 10-Q for the quarter ended March 31, 2011 and our 2010 Form 10-K, each filed with the SEC You are encouraged to review other important risk factors on our web site at www.acurapharm.com under the link, "Company Risk Factors" and detailed in our filings with the SEC. We assume no obligation to update any forward-looking statements as a result of new information or future events or developments. Our press releases may be reviewed at www.acurapharm.com.