



September 20, 2012

Acura Pharmaceuticals Announces Paragraph IV ANDA Filing for OXECTA(R)

PALATINE, IL--(Marketwire - Sep 20, 2012) - Acura Pharmaceuticals, Inc. (NASDAQ : ACUR), a specialty pharmaceutical company developing products intended to address [medication abuse and misuse](#), today announced that it has received notification from a generic sponsor of the filing of an Abbreviated New Drug Application (ANDA) for a generic drug listing Pfizer Inc.'s OXECTA (oxycodone HCl) Tablets CII as the reference listed drug. OXECTA is covered by U.S. patents issued to Acura and licensed to Pfizer. The notification includes a Paragraph IV certification indicating the generic sponsor believes Acura's patents are invalid, unenforceable or not infringed. Acura intends to take appropriate action to enforce its intellectual property.

About Acura Pharmaceuticals

Acura Pharmaceuticals is a specialty pharmaceutical company engaged in the research, development and commercialization of product candidates intended to address [medication abuse and misuse](#), utilizing its proprietary AVERSION[®] and IMPEDE[™] technologies. In June 2011, the U.S. Food and Drug Administration approved OXECTA[®] which incorporates the AVERSION technology. The Company has a development pipeline of additional AVERSION technology products including other opioids and its IMPEDE technology for pseudoephedrine hydrochloride products.

The trademark OXECTA[®] is owned by Pfizer Inc.

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. 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. Forward-looking statements may include, but are not limited to, our and our licensee's ability to successfully launch and commercialize our products and technologies including OXECTA[®] Tablets and Nexafed[®] Tablets, the price discounting that may be offered by Pfizer for OXECTA[®], the ability of us or our licensee's to obtain necessary regulatory approvals and commercialize products utilizing our technologies and the market acceptance of and competitive environment for any of our products, expectations regarding potential market share for our products and the timing of first sales, our ability to enter into additional license agreements for our other product candidates, the ability to avoid infringement of patents, trademarks and other proprietary rights of third parties, and the ability of our patents to protect our products from generic competition, and the ability to fulfill the 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, the results of laboratory and clinical studies we may complete in the future to support FDA approval of our product candidates and the sufficiency of our development to meet over-the-counter, or OTC, Monograph standards as applicable, the adequacy of the development program for our product candidates, including whether additional clinical studies will be required to support FDA approval of our product candidates, changes in regulatory requirements, adverse safety findings relating to our product candidates, whether the FDA will agree with our analysis of our clinical and laboratory studies and how it may evaluate the results of these studies or whether further studies of our product candidates will be required to support FDA approval, whether or when we are able to obtain FDA approval of labeling for our product candidates for the proposed indications and will be able to promote the features of our abuse discouraging technologies, whether our product candidates will ultimately deter abuse in commercial settings and whether our Impede technology will disrupt the processing of pseudoephedrine into methamphetamine. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail in our filings with the Securities and Exchange Commission.

Contact:

Acura Pharmaceuticals, Inc.
for Acura Investor Relations
[Email Contact](#)

847-705-7709

for Acura Media Relations

[Email Contact](#)

847-705-7709