December 20, 2012

Acura Pharmaceuticals, Inc. Submits Investigational New Drug Application

Request to Commence Clinical Investigation

PALATINE, IL -- (Marketwire) -- 12/20/12 -- Acura Pharmaceuticals, Inc. (NASDAQ: ACUR) today announced that an Investigational New Drug application ("IND") has been filed with the U.S. Food and Drug Administration (FDA) to allow clinical testing of Acura's hydrocodone bitartrate with acetaminophen formulated with Aversion® Technology. Clinical testing can commence under the IND 30 days following the IND filing unless questions are raised by the FDA. An open IND is required for Acura to initiate intranasal abuse liability testing in recreational drug users of the crushed drug product.

This study is part of a comprehensive development program we intend to complete in anticipation of submitting a 505(b)(2) NDA for our hydrocodone/acetaminophen product in the first half of 2014. The plan also includes:

- a pharmacokinetic study demonstrating dose proportionality and evaluating the food effect;
- a battery of laboratory studies demonstrating extraction, syringing and particle size characteristics;
- a pharmacokinetic study to establish a bridge to a new contract manufacturer; and
- an assessment of the routes of abuse of hydrocodone products.

Acura continues to evaluate possible partnering of our Aversion development products with alternative strategic partners.

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.

In December, 2012 the Company commenced commercialization of Nexafed® [pseudoephedrine hydrochloride (HCl)] a 30 mg immediate-release abuse-deterrent decongestant. The next generation pseudoephedrine tablet combines effective nasal congestion relief with IMPEDE™ technology, a unique polymer matrix that disrupts the conversion of pseudoephedrine into th dangerous drug, methamphetamine.

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®, our and our licensee's ability to obtain necessary regulatory approvals and commercialize products utilizing our technologies and the market acceptance of and competitive environment for any of our products, the willingness of wholesalers and pharmacies to stock Nexafed® Tablets, 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, our exposure to product liability and other lawsuits in connection with the commercialization of our products, the increased cost of insurance and the availability of product liability insurance coverage, 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, our ability to protect and enforce our patent rights in any paragraph IV patent infringement litigation, 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.

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