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Acura Pharmaceuticals Provides Development Update on Its LIMITX(TM) Abuse Deterrent Technology

Clinical Testing on LTX-04 to Commence in the First Quarter 2016

PALATINE, IL -- (Marketwired) -- 02/01/16 --

Acura Pharmaceuticals, Inc. (NASDAQ: ACUR), a specialty pharmaceutical company innovating abuse deterrent drugs, today announced that clinical testing of its lead LIMITX™ oral abuse deterrent drug candidate using the opioid hydromorphone HCl (LTX-04) is allowed to proceed under an Investigational New Drug Application (IND) the Company filed with the Food and Drug Administration on December 30, 2015. LIMITX is designed to retard the release of the product's active ingredient as more and more tablets are orally consumed thereby limiting peak blood concentrations of the opioid. The Company is in the process of manufacturing clinical trial materials and expects to commence enrollment in the first clinical study of LTX-04, Study AP-LTX-400, later in the first quarter of 2016.

Study AP-LTX-400, will be a Phase 1 exploratory pharmacokinetic study to evaluate the plasma absorption of hydromorphone from orally administered tablets in the fasted state. Study AP-LTX-400 will target to complete approximately 48 healthy subjects in two separate cohorts, with 24 subjects in each cohort. For safety, all subjects will receive a naltrexone block prior to and during dosing to blunt any serious adverse effects that may result from the doses of hydromorphone.

Subjects in Cohort 1 will be further randomized into three dosage groups taking either one, two or three 2mg hydromorphone tablets. Each Cohort 1 subject will take two different test formulations of LTX-04 and DILAUDID brand of hydromorphone HCl. The objective of Cohort 1 will be to determine if the LTX- 04 test products are delivering the appropriate amount of hydromorphone into the blood stream to treat pain. Additionally, Cohort 1 may begin assessing the extent that the release of hydromorphone active ingredient from the LTX-04 tablets is retarded as the dose level increases.

Following the results of Cohort 1, Cohort 2 subjects will be randomized into three dosage groups taking four, six or eight 2mg hydromorphone tablets. Each Cohort 2 subject will take one test formulation of LTX-04 selected based on the results of Cohort 1 and DILAUDID. The objective of Cohort 2 will be to further explore the extent the release of hydromorphone active ingredient from LTX-04 tablets is retarded as the dose level increases to abusive levels. A safety assessment of LTX-04 will be made from both study cohorts.

Acura expects topline study results from Study AP-LTX-400 to be available in the first half of 2016.

LTX-04 is being developed in part with a grant from the National Institute on Drug Abuse (NIDA). NIDA is not responsible for any research results.

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 LIMITX™, AVERSION® and IMPEDE® Technologies. LIMITX contains ingredients that are intended to reduce or limit the rate or extent of opioid release when multiple tablets are ingested. AVERSION contains polymers that cause the drug to gel when dissolved; it also contains compounds that irritate the nasal passages if the product is snorted. IMPEDE is designed to disrupt the processing of pseudoephedrine from tablets into methamphetamine.

OXAYDO® (oxycodone HCl immediate-release tablets) which incorporates the AVERSION Technology, is FDA approved and marketed in the U.S. by our partner Egalet Corporation.

Acura markets NEXAFED® and NEXAFED® Sinus, which are pseudoephedrine containing products that utilize the IMPEDE Technology.

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 forwarding-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 results, performance, or achievements expressed or implied by such forward-looking statements. Forward-looking statements may include, but are not limited to, the expected results of Study AP-LTX-400 and the date by which such study results will be available, whether LIMITX will retard the release of opioid active ingredients as dose levels increase, our ability to fund or to obtain funding for our continued operations, our 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, our and our licensee's ability to successfully launch and commercialize our products and technologies including OXAYDO Tablets and NEXAFED products, the price and price discounting that may be offered by Egalet for OXAYDO, 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 pharmacies to stock our NEXAFED products, expectations regarding potential market share for our products, 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, 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, including our LIMITX 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 formulated with our Aversion or LIMITX technologies 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," "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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