December 14, 2016

Acura Pharmaceutical Provides Development Update on its LIMITx(TM) Technology

FDA Provides Advice on Further Development of LTX-04

PALATINE, IL -- (Marketwired) -- 12/14/16 -- Acura Pharmaceuticals, Inc. (NASDAQ: ACUR), a specialty pharmaceutical company innovating abuse deterrent drugs, today announced that the U.S. Food and Drug Administration (FDA) has provided the Company with advice on the continued development of its product candidate LTX-04 (hydromorphone HCI) which utilizes the Company's novel LIMITx™ technology that is intended to provide safeguards against accidental overdose and oral excessive tablet abuse (Oral ETA).

The FDA confirmed the Company's stated direction to reformulate LTX-04 to provide greater levels of drug in the blood stream following an intended 1 or 2 tablet dose, noting a scientific bridge of bioequivalence to DILAUDID will support a finding of safety and efficacy. In Study AP-LTX-400 (Study 400), the LTX-04 tablets delivered approximately 50% of the maximum drug concentration in the blood stream (Cmax) following intended 1 and 2 tablet doses compared to DILAUDID.

In Study 400, the Company observed an average 20% reduction in maximum drug concentration in the blood stream under Oral ETA conditions, when 3, 4, 6, and 8 tablets were ingested. The FDA recommended the Company, in the future, identify studies to measure the clinical impact on abuser behavior and overdose outcomes (such as drug liking and respiratory depression) associated with the LTX-04 reductions in Cmax. The FDA did not disagree with the Company's approach to measuring the reduction in Cmax but did note modifications made to the data to adjust Cmax based on the 1 and 2 tablet dose make it difficult to draw conclusions about individual patients or patient subpopulations.

In its subject level analysis of Study 400, the Company identified a subpopulation (53% of study subjects) that absorbed the drug in DILAUDID faster and to a greater extent and this "faster" subpopulation had more profound reductions in Cmax when taking LTX-04, including a 38% average reduction in Cmax with a 66% maximum reduction observed in 12% of the subpopulation. The FDA noted that to label a product for a particular patient subpopulation, prescribers should be able to understand that only a subset of their patients may benefit from use of the product.

The FDA's advice also identified longer term studies necessary for submitting a New Drug Application for LTX-04, including in vitro extraction studies, drug interaction studies, additional pharmacokinetic studies assessing the impact of food and beverages, and, if abuse-deterrent labeling is requested, a category 3 abuse liability study.

The patented LIMITx technology works by neutralizing stomach acid as increasing numbers of tablets are swallowed and relying on stomach acid to play a role in the release and subsequent systemic absorption of the active ingredient from micro-particles contained in the tablets.

Acura intends to advance new formulations of LTX-04 tablets to a second pharmacokinetic study which is expected to start in late first quarter of 2017 after Acura addresses certain formulation stability issues. The Company has already identified formulations that they believe will release drug faster at the 1 and 2 tablet dose. The Company intends to develop LTX-04 through proof of concept and then rapidly advance a formulation of a product with a greater prevalence of Oral ETA, such as immediate-release hydrocodone with acetaminophen.

LTX-04 was developed in part with a grant from the National Institute on Drug Abuse (NIDA). NIDA is not responsible for the results of any of the Company's research. The LTX-04 development program is also designated as Fast Track by the FDA for its potential to address an unmet medical need.

To further discuss these results Acura's management will host a conference call on Thursday, December 15, 2016 at 8:30 a.m. ET. To participate in the live conference call, please dial ***888-632-3381*** (U.S. and Canada) five to ten minutes prior to the start of the call. The participant passcode is ***7979444***. A replay of the call will be available beginning December 15, 2016 and ending on December 31, 2016. The replay participant code is ***7979444***.

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 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 ability to fund or obtain funding for our continuing operations, including the development of our products utilizing our LIMITX and Impede® technologies;
- the expected results of clinical studies relating to LTX-04 or any successor product candidate, the date by which such study results will be available and whether LTX-04 or any successor product candidate will ultimately receive FDA approval;
- whether LIMITX will retard the release of opioid active ingredients as dose levels increase;
- whether we will be able to reformulate LTX-04 or any successor product candidate to provide an efficacious level of drug when one or two tablets are taken;
- whether we will be able to reformulate LTX-04 or any successor product candidate to improve its abuse deterrent performance;
- whether the extent to which products formulated with the LIMITX technology deter abuse will be determined sufficient by the FDA to support approval or labelling describing abuse deterrent features;
- whether our LIMITX technology can be expanded into extended-release formulations;
- our and our licensee's ability to successfully launch and commercialize our products and technologies, including Oxaydo® Tablets and our Nexafed® products;
- our and our licensee's ability to obtain necessary regulatory approvals and commercialize products utilizing our technologies;
- the market acceptance of, timing of commercial launch and competitive environment for any of our products;
- expectations regarding potential market share for our products;
- our ability to develop and enter into additional license agreements for our product candidates using our technologies;
- the ability to avoid infringement of patents, trademarks and other proprietary rights of third parties;
- the ability of our patents to protect our products from generic competition and our ability to protect and enforce our patent rights in any paragraph IV patent infringement litigation;
- 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 process to meet over-the-counter ("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 commercialized products or product candidates in development;
- whether the FDA will agree with our analysis of our clinical and laboratory studies;
- 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 whether we will be able to promote the features of our abuse discouraging technologies; and
- whether Oxaydo or our Aversion and LIMITX product candidates will ultimately deter abuse in commercial settings and whether our Nexafed products and Impede technology product candidates 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," "indicates", "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.

DILAUDID is a trademark of Purdue Pharma L.P.

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