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Acura Pharmaceutical's LIMITX(TM) Technology Successfully Confirms Oral Abuse Deterrence Capabilities

Topline Results From Study AP-LTX-400 Cohort 2

PALATINE, IL -- (Marketwired) -- 06/08/16 -- Acura Pharmaceuticals, Inc. (NASDAQ: ACUR), a specialty pharmaceutical company innovating abuse deterrent drugs, today announced that topline results from cohort 2 of clinical study AP-LTX-400 (Study 400) confirmed that LTX-04P tablets, a hydromorphone hydrochloride immediate-release tablet using the Company's new LIMITX oral abuse deterrent technology, successfully retarded the release of the active opioid ingredient when four, six and eight intact tablets were ingested. The Company previously announced similar abuse deterrent findings from cohort 1 of Study 400 for a 3 tablet dose of LTX-04P but that additional formulation development will be required for LTX-04P to deliver a sufficient amount of the active ingredient to patients when one or two tablets are administered. The Company expects to resume clinical testing of a new formulation of LTX-04 in the fourth quarter of 2016 following completion of ongoing reformulation work and a discussion with the U.S. Food and Drug Administration (FDA) regarding the results of Study 400.

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 of the active ingredient from micro-particles contained in the tablets.

Cohort 2 of Study 400 studied 4, 6 and 8 tablet dosage subgroups of LTX-04P against the marketed comparator product, DILAUDID. Cohort 1 studied 1, 2 and 3 tablet dosage subgroups. Study 400 measured the rate and extent of absorption of the active drug ingredient into the blood stream with the maximum drug concentration, or Cmax, typically associated with an increase in drug abuse. Subjects in Study 400 had an average 22% reduction in relative Cmax when 3 or more tablets were ingested as shown in the table below.

Study 400 - Mean Ratio of Cmax (ng/mL) by Dosing Group Compared to the 1 Tablet Group for the Same Formulation				
	Dosing in mg	DILAUDID	LTX-04P	Change
2 Tablet Group	2x	1.9x	2.2x	15%
3 Tablet Group	3x	4.8x	3.8x	-22%
4 Tablet Group	4x	6.4x	4.8x	-25%
6 Tablet Group	6x	6.2x	5.2x	-15%
8 Tablet Group	8x	8.4x	6.8x	-18%
Average 3-8				-22%

All Subjects in cohort 2 had extent of drug absorption (measured by AUC) for LTX-04P comparable to DILAUDID when the same number of tablets were ingested. Likewise, the time to maximum plasma concentration, or Tmax, was comparable at all doses. All doses in Study 400 were generally well tolerated with no serious adverse event reported.

Dr. Al Brzeczko, Acura's Vice President of Technical Affairs commented, "We are excited the dosing levels studied in cohort 2 of Study 400 confirmed the LIMITX technology concept of reducing Cmax as higher, more abused doses are ingested. Study 400 provided us with a wealth of data that we will mine to adjust our formulation to achieve better performance for the one and two tablet doses. We will also look to see if we can improve upon the abuse deterrent performance as well."

"To see this level of abuse deterrence with our first test formulation is wonderful for this new technology," noted Bob Jones, President and CEO of Acura. "We look forward to completing our analysis of Study 400, finishing our reformulation and getting back in the clinic as soon as possible."

The Company continues to advance its reformulation work on the LIMITX technology micro-particles to improve the drug delivery with one and two tablets and hopes to have a dialogue with the FDA regarding these results and the next clinical phase under its Fast Track development designation for LTX-04.

About Study AP-LTX-400

StudyAP-LTX-400 (Study 400) is a two cohort, open label, crossover design pharmacokinetic study in healthy adult subjects. Cohort 1 enrolled 30 subjects who were randomized into three subgroups of 10 taking either 1, 2 or 3 tablets. Each subgroup subject orally swallowed the planned number of tablets in a randomized manner taking single doses of two different test formulations of LTX-04 (designated as LTX-04P and LTX-04S) and the marketed drug DILAUDID as a comparator. All tablets contained 2mg of hydromorphone hydrochloride. The 1, 2 and 3 tablets subgroups in Cohort 1 completed 8, 10 and 8 subjects, respectively.

Cohort 2 enrolled 30 subjects who were randomized into three subgroups of 10 taking either 4, 6 or 8 tablets. Each subgroup subject orally swallowed the planned number of tablets in a randomized manner taking single doses of LTX-04P and the marketed drug DILAUDID as a comparator. The 4, 6 and 8 tablets subgroups in Cohort 2 completed 8, 9 and 8 subjects, respectively.

All tablets contained 2mg of hydromorphone hydrochloride. All subjects received doses of naltrexone and there was a one week washout between doses. Blood samples were taken at pre-designated time-points after dosing and were subsequently analyzed for the concentration of hydromorphone contained in the sample. All subjects in Cohort 1 had continuous pH (a measure of acid concentration) monitoring of their stomach acid. The objective of Cohort 1 was to determine if adequate active drug entered the blood stream when one or two LIMITX tablets were swallowed and to begin assessing the ability of the LIMITX technology to start retarding the release of active ingredients when three tablets are ingested. The objective of Cohort 2 was to further explore the extent the release of the hydromorphone active ingredient from LTX-04P tablets is retarded as the dose level increases to abusive levels. A safety assessment of LIMITX Hydromorphone will be made from both study cohorts.

LTX-04 is being 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 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 live conference call and webcast at 8:30 am ET on Thursday, June 9, 2016. The presentation will be webcast live and may be accessed by visiting the Company's website, Acurapharm.com and selecting the "News and Events" option under the "Investors" tab. For those wishing to listen only you may dial ***1-888-576-4398*** with passcode ***1705487***. A replay of the webcast will be available for 60 days on the Acura website.

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-04P, the date by which such study results will be available and whether LTX-04P 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-04P to provide an efficacious level of drug when one or two tablets are taken;

- whether we will be able to reformulate LTX-04P 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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