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Acura Pharmaceutical's Limitx(TM) Technology Successfully Demonstrates Oral Abuse Deterrence

Conference Call and Webcast Scheduled to Discuss Results on Thursday, April 14, 2016

PALATINE, IL -- (Marketwired) -- 04/13/16 -- Acura Pharmaceuticals, Inc. (NASDAQ: ACUR), a specialty pharmaceutical company innovating [abuse deterrent drugs](#), today announced that topline interim results from clinical study AP-LTX-400 demonstrated one test formulation of LTX-04, a hydromorphone hydrochloride immediate-release tablet using the Company's new LIMITX oral abuse deterrent technology, successfully demonstrated the release of the active opioid ingredient was reduced when three intact tablets were ingested but that additional formulation development will be required for LTX-04 to deliver a sufficient amount of the active ingredient to patients when one or two tablets are administered. Study AP-LTX-400 is a two cohort pharmacokinetic study with today's results limited to the first of the two cohorts. The second cohort of the study is expected to commence later this month.

The patented LIMTX 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. "This was a successful study result as we were able to observe the concept that neutralizing stomach acid can be used to regulate drug delivery starting with as few as three tablets," commented Dr. Al Brzezko, Acura's Vice President of Technical Affairs and a co-inventor of the LIMITX technology. "Demonstrating the concept that neutralizing stomach acid can be used to regulate drug delivery was a key objective for this study -- which we expected to demonstrate in cohort 2 of the study. It's definitely a bonus to begin to see that signal in cohort 1. At the same time, we now better understand the release profile of the micro-particles that contain the drug and believe we can reformulate the micro-particles to achieve greater release of the active ingredient when one or two tablets are taken," he added.

Study AP-LTX-400 studies two different test formulations of LTX-04; designated as LTX-04P and LTX-04S. Each formulation of LTX-04 contains the same micro-particles and the same amount of active ingredient. LTX-04S contains approximately 45% less acid neutralizing capacity than LTX-04P. The different formulations were designed to test the oral abuse deterrent parameters of the LIMITX technology.

Subjects taking 3 tablets of the marketed comparator product, DILAUDID, had a maximum plasma concentration of the active ingredient, or C_{max}, 4.8 times higher than subjects taking 1 tablet. Likewise, the C_{max} for LTX-04S was 4.7 times higher for the 3 tablet group compared to the 1 tablet group. Both of these groups had stomach acid pH between 2 and 4 at 15 minutes post-dose. However, the 3 tablet LTX-04P dose achieved an average stomach acid pH of 4.7 post-dose and the C_{max} was only 3.8 times as high as the single tablet dose, an estimated 22% reduction in C_{max}. The increase in stomach pH demonstrated with LTX-04P was expected to correlate to a slowing of the release of active ingredient from the tablet's micro-particles resulting in a reduction of C_{max}, among other measures. Drug abuse is typically associated with an increase in C_{max}.

Subjects taking one or two tablets of both LTX-04 formulations had comparable extent of drug absorption (measured by AUC) as the same number of tablets of DILAUDID. However, these tablets delivered approximately 50% less peak plasma concentration (C_{max}) than DILAUDID. As such, the LTX-04 test formulations were considered to not have achieved equivalent blood levels of drug and will require further development. All study drugs were generally well tolerated and no serious adverse events were observed.

Bob Jones, President and CEO of Acura noted, "The cohort 1 results validate that the LIMITX oral abuse deterrent technology concept works in humans and adds a third definitive abuse deterrent technology to our portfolio. As oral abuse by swallowing excessive numbers of tablets is considered to be the most prevalent route of opioid abuse, LIMITX provides a novel advancement in the work to develop abuse deterrent formulations." He added, "While cohort 1 of Study AP-LTX-400 did not achieve all its objectives, we learned a lot about our technology and are now encouraged that we may be able to expand the LIMITX technology into extended-release formulations as well as immediate-release products."

The Company intends to complete cohort 2 of Study AP-LTX-400 in which subjects will take 4, 6 and 8 tablets testing the LTX-04P formulation to confirm the abuse deterrent results observed in cohort 1. Cohort 2 is expected to commence dosing in late April 2016 with topline results expected in late June 2016. The Company intends to immediately begin reformulation work on the LIMITX technology micro-particles to improve the drug delivery with one and two tablets. Finally, the Company

hopes to have a dialogue with the US Food and Drug Administration regarding these results and the next clinical phase under its Fast Track development designation for LTX-04.

About Study AP-LTX-400

Study AP-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. All subjects received doses of naltrexone and there was a one week washout between doses. Blood samples are taken at pre-designated time-points after dosing and are subsequently analyzed for the concentration of hydromorphone contained in the sample. All subjects in Cohort 1 have 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 LIMIT technology to start retarding the release of active ingredients when three tablets are ingested.

Subjects in Cohort 2, which has not yet enrolled, will be randomized into three subgroups taking four, six or eight tablets. Each Cohort 2 subject will take one test formulation of LTX-04 and DILAUDID. The objective of Cohort 2 will be to further explore the extent the release of the hydromorphone active ingredient from LTX-04 tablets is retarded as the dose level increases to abusive levels. A safety assessment of LIMITX Hydromorphone will be made from both study cohorts.

Acura expects complete topline study results from Study 400 to be available in June 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 the results of any of the research. The LTX-04 development program is also designed as Fast Track by the U.S. Food and Drug Administration 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, April 14, 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 **1-888-572-7034** with passcode **8154147**. 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:

- 1 the expected results of clinical studies relating to LTX-04, the date by which such study results will be available and whether LTX-04 will ultimately receive FDA approval;
- 1 whether LIMITX will retard the release of opioid active ingredients as dose levels increase;
- 1 whether we will be able to reformulate LTX-04 to provide an efficacious level of drug when one or two tablets are taken;

- | whether our LIMITX technology can be expanded into extended-release formulations;
- | our ability to fund or obtain funding for our continuing operations, including the development of our products utilizing our LIMITX and Impede® technologies;
- | 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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