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Acura Pharmaceuticals Advances LTX-03 and its LIMITx™ Technology

PALATINE, Ill., Oct. 09, 2017 (GLOBE NEWSWIRE) -- Acura Pharmaceuticals, Inc. (OTCQB:ACUR), a specialty pharmaceutical company innovating abuse deterrent drugs, today announced that topline results from clinical study AP-LTX-300 (Study 300) for its LIMITx™ oral abuse deterrent drug LTX-03 demonstrated rapid release of drug from the micro-particle formulation providing expected therapeutic drug levels in the bloodstream for a single dose. In previous studies, Acura demonstrated the LIMITx micro-particles reduced peak blood concentrations of drug by 50 to 65% when multiple tablets are ingested. Due to erratic release of drug from the over-encapsulated tablets used in Study 300, the Company was unable to reliably identify the precise buffer level for a single LIMITx tablet and plans to execute another dose ranging study without using over-encapsulation. The Company expects to complete this next study in the first quarter of 2018.

The patented LIMITx technology works by neutralizing stomach acid with buffering ingredients as increasing numbers of tablets are swallowed and relies 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.

Study 300 was a parallel design pharmacokinetic study testing Acura's LIMITx formulation LTX-03 in 56 healthy adult subjects divided evenly into 7 groups. One group swallowed a single Norco® tablet, the marketed comparator or reference drug, while the remaining 6 groups swallowed a single LIMITx micro-particle tablet with increasing buffering amounts starting with no buffer to determine the appropriate single tablet buffer amount. All 56 subjects completed the study and the doses were generally well tolerated with no serious adverse events. LTX-03 is a combination of hydrocodone bitartrate and acetaminophen.

In Study 300, a single LTX-03 dose formulated without any buffer achieved a peak blood concentration (Cmax) of hydrocodone of 82% of the reference drug. Comparatively, the Cmax of acetaminophen in LTX-03 from the same non-buffered dose was 63% of the reference drug. The acetaminophen Cmax was 100% of the reference drug across all doses in the study indicating the non-buffered LIMITx cohort was apparently unduly affected by the over-encapsulation.

"With acetaminophen release and absorption equivalent to Norco® across the study, the erratic release from the capsules was very evident in the non-buffered dosing arm as the absorption of both acetaminophen and hydrocodone were both comparatively low. However, with the hydrocodone Cmax at 82% of the reference drug, we are encouraged that bioequivalence of both active ingredients may be achievable in future studies without the effects of the capsules," commented Dr. Al Brzeczko, Acura's Vice President of Technical Affairs. "Even without bioequivalence, we believe these study results demonstrate adequate therapeutic blood levels of hydrocodone at a single tablet dose to support an analgesic efficacy study if needed."

All ingredients in the study, including the reference tablets, used a not uncommon practice of over-encapsulation with a standard gelatin capsule to allow dosing of multiple LIMITx test articles simultaneously to replicate the action of a single tablet dose. The Company observed the time to maximum blood concentration (Tmax) for the over-encapsulated reference drug compared to published standards was 60 (183%) and 50 (188%) minutes longer for hydrocodone and acetaminophen, respectively. Following a review of subject data, the Company concluded the over-encapsulation unduly delayed the release of drug and also released drug very erratically from subject-to-subject. The Company deemed the Study 300 results pertaining to the identification of the appropriate level of buffering agent to include in each tablet as inconclusive since the LIMITx system is known to be sensitive to timing of release of its ingredients. The Company is developing plans to conduct a second buffer dose ranging study foregoing over-encapsulation to guide the final formulation of the tablet with buffers. This study is expected to commence in the fourth quarter of 2017 with topline results in the first quarter of 2018.

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.

NEXAFED® and NEXAFED® Sinus, which are pseudoephedrine containing products that utilize the IMPEDE Technology, are marketed in the U.S. by our partner MainPointe Pharmaceuticals.

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-03 or any successor product candidate, the date by which such study will complete and the results will be available and whether LTX-03 or any successor product candidate will ultimately receive FDA approval;
- the ability of LTX-03 single tablets to demonstrate analgesic efficacy in a clinical study;
- the ability of LTX-03 to achieve bioequivalence in future studies;
- the ability to identify a suitable buffer level for LTX-03;
- whether LIMITx will retard the release of opioid active ingredients as dose levels increase;
- whether we will be able to reformulate LTX-03 or any successor product candidate to provide an efficacious level of drug when one or two tablets are taken;
- whether a reformulated LIMITx formulation that achieves an efficacious level of drug will continue to demonstrate acceptable abuse deterrent performance;
- whether we will be able to reformulate LTX-03 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;
- 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;
- 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 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.

Contact:
for Acura Investor Relations
investors@acurapharm.com
847-705-7709

 Primary Logo

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