September 11, 2017

Acura Pharmaceuticals Presenting New LIMITx™ Clinical Data at the 19th Annual Rodman & Renshaw Conference

PALATINE, Ill., Sept. 11, 2017 (GLOBE NEWSWIRE) -- Acura Pharmaceuticals, Inc. (OTCQB:ACUR), a specialty pharmaceutical company innovating abuse deterrent drugs, today announced the results from the previously undisclosed exploratory arm of its second LIMITx™ clinical study, study AP-LTX-401 (Study 401). Bob Jones, President and Chief Executive Officer, will present the results at the 19th Annual Rodman & Renshaw Global Investment Conference today at 1:45 p.m. Eastern Time. The presentation will be webcast live and may be accessed by visiting Acura's website at www.acurapharm.com.

Study 401 dosed fasted subjects with 7 tablets of LTX-04P3, a test version of Acura's LTX-04 LIMITx oral excessive tablet abuse deterrent technology with a comparison to 7 tablets of commercially available comparable hydromorphone hydrochloride tablets. The exploratory arm added an ingredient, simultaneously dosed with 7 LTX-04P3 tablets, known to delay gastric emptying and to potentially increase the retention of the LIMITx buffering ingredients in the stomach.

The exploratory arm demonstrated an increase in time to maximum concentration of drug in the bloodstream (lnTmax) to slightly over 2 hours compared to 43 minutes for hydromorphone and 73 minutes for LTX-04P3 alone. Peak concentration of drug in the bloodstream (lnCmax) for the exploratory arm was 3.74 ng/mL compared to 6.73 for hydromorphone and 2.49 for LTX-04P3 alone.

The 7 tablet cohort in Study 401 was a crossover pharmacokinetic design in fasted, healthy adult subjects. 30 subjects completed the hydromorphone arm, 13 subjects completed the LTX-04P3 arm, and 15 subjects completed the LTX-04P3 exploratory arm. There were no serious adverse events with adverse events observed consistent with those known to be associated with hydromorphone.

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.

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-04 or any successor product candidate, the date by which such study will complete and the 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 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-04 or any successor product candidate to improve its abuse deterrent performance;
- whether the results from LTX-04 studies will translate into similar results for an immediate release hydrocodone bitartrate acetaminophen product, which is the product we intend to take forward in the near term;
- whether the FDA will accept delays in gastric emptying as a viable component of abuse deterrent methodology;
- 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.

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