



April 12, 2016

## **Acura Pharmaceuticals Announces FDA Fast Track Designation for the Development of LTX-04**

### **Lead LIMITX Oral Abuse Deterrent Development Program**

PALATINE, IL -- (Marketwired) -- 04/12/16 -- 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 designated as a Fast Track development program the investigation of LTX-04, Acura's hydromorphone HCl tablets utilizing its oral abuse deterrent LIMITX technology, for the management of pain in patients where an opioid analgesic is appropriate.

FDA's Fast Track is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. Filling an unmet medical need is defined as providing a therapy where none exists or providing a therapy which may be potentially better than available therapy, including avoiding serious side effects of an available therapy.

A drug that receives Fast Track designation is eligible for, among other things, more frequent meetings and communications with the FDA and eligibility for accelerated approval and priority review, if relevant criteria are met. More frequent communication with FDA aids in the drug's development plan, ensures collection of appropriate data needed to support drug approval, and provides FDA insight on clinical trial design and can assure that questions and issues are resolved quickly, often leading to earlier drug approval and access by patients.

### **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:

- | 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;
- | whether LIMITX will retard the release of opioid active ingredients as dose levels increase;
- | 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 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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