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Acura Pharmaceuticals to Develop Abuse Deterrent Hydrocodone With Acetaminophen Tablets With Limitx(TM) Technology

Immediate-Release Tablets Intended to Address Excess Oral Consumption

PALATINE, IL -- (Marketwired) -- 04/09/15 --

Acura Pharmaceuticals Inc. (NASDAQ: ACUR), announced today that it is initiating development of an immediate-release hydrocodone bitartrate with acetaminophen tablet ("hydrocodone/APAP") incorporating Acura's novel LIMITX™ abuse deterrent technology. Hydrocodone/APAP, with over 135 million dispensed prescriptions in 2014 in the United States, is the largest prescribed opioid to treat moderate to severe pain. It also is the single most abused prescription opioid, predominately by swallowing multiple tablets. LIMITX is designed specifically to address this route of abuse.

The Food and Drug Administration's (FDA) April 2015 Abuse-Deterrent Opioids Evaluation and Labeling Guidance singles out immediate-release combination opioids with acetaminophen as being predominately abused by the oral route and that reducing nasal snorting of these products may not be meaningful. Development of the Company's LIMITX technology is currently being supported by a grant from the National Institute on Drug Abuse of the National Institutes of Health (NIH) to develop an immediate-release hydromorphone tablet. The Company intends to initiate formulation development of the LIMITX hydrocodone/APAP tablet upon the conclusion of formulation optimization of the LIMITX hydromorphone product. Acura had previously advanced the development of a hydrocodone/APAP product using our AVERSION® technology, which was designed to deter nasal snorting, but intends to indefinitely suspend those efforts.

"Based on the recent FDA Guidance as well as comments made by the former-FDA Commissioner at a March 2015 Appropriation Hearing, we believe the best course for Acura is to develop immediate-release acetaminophen combination opioids with our novel LIMITX technology", said Bob Jones, President and CEO of Acura. "We are pleased to be partnered with the NIH on our LIMITX technology and believe it may also be applicable to snorting abuse, which we continue to believe is a route of abuse for these products that needs addressing."

About Limitx™ Technology

LIMITX technology is an early stage technology separate and apart from the Company's other abuse deterrent technologies, Aversion® and Impede®. LIMITX is a novel formulation of common pharmaceutical ingredients intended to address abuse by excess oral consumption of multiple tablets. In proof of concept laboratory tests, LIMITX demonstrated the ability to limit the release of the active ingredient from tablets when multiple tablets are simultaneously introduced into simulated gastric fluid. Acura has patents pending with the U.S. Patent and Trademark office covering its LIMITX technology.

Phase I Research on the Company's hydromorphone tablet utilizing LIMITX technology is supported by the National Institute on Drug Abuse of the National Institutes of Health under Award Number R44DA037921. The results and content of any such research is solely the responsibility of Acura and does not necessarily represent the official views of the National Institutes of Health.

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.

In June 2011, the U.S. Food and Drug Administration approved OXAYDO™ (oxycodone HCl immediate-release tablets) which incorporates the AVERSION Technology. On January 7, 2015, we entered into a Collaboration and License Agreement with Egalet US, Inc. and Egalet Ltd., each a subsidiary of Egalet Corporation, pursuant to which we exclusively licensed to Egalet worldwide rights to manufacture and commercialize OXAYDO.

Acura also 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. Forwarding-looking statements may include, but are not limited to, the results of our clinical development of our hydrocodone/APAP product using our LIMITX technology, whether our hydrocodone/APAP formulation will lead to a commercial product, whether or when we are able to obtain FDA approval of this product candidate, whether we will be able to promote the abuse-deterrent features of our LIMITX technology, whether our product candidates utilizing our LIMITX technology will actually deter excess oral consumption or nasal snorting, and whether competitors will develop and commercialize products using alternative abuse-deterrent technologies that are more effective than our LIMITX technology. Such forwarding-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. 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. Unless required by law, we undertake no obligation to update or revise any forward-looking statements to reflect new information or future events or developments.

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