September 15, 2014

Acura Pharmaceuticals Submits Formal Dispute Resolution Request With FDA Regarding Hydrocodone Bitartrate With Acetaminophen Tablets

PALATINE, IL -- (Marketwired) -- 09/15/14 -- Acura Pharmaceuticals Inc. (NASDAQ: ACUR), announced today that it has submitted a formal dispute resolution request with the FDA for Vycavert®, its abuse deterrent formulation of hydrocodone and acetaminophen tablets. The dispute pertains to the FDA's determination that nasal snorting abuse of hydrocodone with acetaminophen products lacks relevance.

By taking this action, Acura is availing itself of the FDA's established appeal process whereby disagreements with conclusions reached by a reviewing Division within the FDA are reviewed above the Division level. FDA guidance stipulates that the FDA respond within 30 days.

Acura believes the available data, as contained in the multiple sources provided to the FDA, strongly supports the conclusion that hydrocodone containing products are known to be abused through snorting, a standard explicitly identified in FDA's January 2013 "Guidance for Industry Abuse-Deterrent Opioids -- Evaluation and Labeling". Acura further believes that such route of abuse results in hospitalizations and poses a significant public health issue.

Bob Jones, Acura's CEO, stated "There are critical public health policy issues being established by FDA with this decision which we believe need further discussion. Hydrocodone containing drugs are widely considered to be our most abused pharmaceutical products and 2.8% of our youths aged 12 to 17 used psychotherapeutic drugs nonmedically in 2012."

There can be no assurance that the dispute resolution will be successful. Even if the Company were to succeed in such proceeding, in order to continue the development of our Vycavert® product we will be required to conduct an additional abuse liability study that will need to demonstrate a statistically significant reduction in Drug Liking, of which no assurance can be provided.

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. IMPEDE® is designed to disrupt the processing of pseudoephedrine from tablets into methamphetamine.

In June 2011, the U.S. Food and Drug Administration approved our oxycodone HCl immediate-release tablets which incorporate the AVERSION® Technology. The Company has a development pipeline of additional AVERSION® Technology products containing other opioids.

In December 2012, the Company commenced commercialization of NEXAFED® [pseudoephedrine hydrochloride (HCl)], a 30 mg immediate-release abuse-deterrent decongestant. The next generation pseudoephedrine tablet combines effective nasal congestion relief with IMPEDE® Technology, a unique polymer matrix that disrupts the conversion of pseudoephedrine into the dangerous drug, methamphetamine.

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 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 results, performance, or achievements expressed or implied by such forward-looking statements. Forward-looking statements may include, but are not limited to:

- the results of our dispute resolution request with the FDA relating to our AVERSION® hydrocodone/acetaminophen product;
- the results of our development of our Limitx™ technology;
- our ability to fund, or obtain funding for, products developed utilizing our Limitx™ technology;
- our ability to enter into a license agreement for our FDA approved AVERSION® oxycodone product;
- our and our licensee's ability to successfully launch and commercialize our products and technologies including

AVERSION® oxycodone and NEXAFED® Tablets;
- the results of our meetings or discussions with the FDA relating to our AVERSION® hydrocodone/acetaminophen product;
- whether we will conduct an additional intranasal abuse liability study on our AVERSION® hydrocodone/ acetaminophen product and, if conducted, whether the results of such study will support the filing of a New Drug Application and/or a claim of intranasal abuse deterrence;
- our and our licensee's ability to obtain necessary regulatory approvals and commercialize products utilizing our technologies;
- the market acceptance of and competitive environment for any of our products;
- the willingness of wholesalers and pharmacies to stock NEXAFED® Tablets;
- expectations regarding potential market share for our products and the timing of first sales;
- our ability to enter into additional license agreements for our AVERSION® Technology product candidates;
- our exposure to product liability and other lawsuits in connection with the commercialization of our products;
- the increasing cost of insurance and the availability of product liability insurance coverage;
- 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 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 product candidates;
- 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 our AVERSION® and Limitx™ product candidates will ultimately deter abuse in commercial settings and whethe our IMPEDE® Technology 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," "indicates," "estimates," "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. 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. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this press release may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

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