May 27, 2014

Acura Pharmaceuticals Provides Update on Its Abuse Deterrent Hydrocodone/Acetaminophen Combination Drug

PALATINE, IL -- (Marketwired) -- 05/27/14 -- Acura Pharmaceuticals, Inc. (NASDAQ: ACUR) today announced the US Food and Drug Administration (FDA) advised the Company that the data from our intranasal abuse liability study AP-ADF-301 (Study 301) for our AVERSION hydrocodone bitartrate with acetaminophen (hydrocodone/APAP) product candidate are insufficient to support an intranasal abuse deterrence claim. The FDA's advice was provided in response to the Company's meeting with the FDA on December 5, 2013 to discuss the results of Study 301. The FDA indicated that a product will have to have an impact on "Drug Liking" to support a claim of abuse-deterrence through a relevant route of abuse. Study 301 failed to achieve a statistically significant reduction in "Drug Liking" (also known as Emax). The FDA's advice also questioned whether the intranasal route is a relevant route of abuse for hydrocodone/APAP products and recommended Acura identify variables that could have impacted the findings from Study 301 before considering or conducting an additional intranasal abuse liability study on our AVERSION hydrocodone/APAP product. Acura previously submitted a report to the FDA on the prevalence of abusing hydrocodone products by intranasal administration and intends to meet with the FDA to discuss the FDA's expectations in this area.

Acura's plans for AVERSION hydrocodone/APAP, including a revised projected timeline for submission of the New Drug Application, will be determined following our meeting with the FDA.

"We are disappointed that our Study 301 data was insufficient to support an intranasal abuse deterrence claim," said Bob Jones, President and CEO of Acura. "Hydrocodone/APAP is generally recognized as the most widely abused drug and our review of available literature indicates that approximately 18% of the general abuse population abuses these products via snorting. Further, we believe this percentage can reach over 70% in some localized markets. We remain committed to developing our AVERSION opioids products to help address the epidemic of prescription drug abuse gripping our country."

About Study 301

Study 301 was a phase II, single-center, randomized, double-blind, 5-period crossover assessment of the abuse liability potential of snorting crushed AVERSION hydrocodone/APAP tablets. Forty subjects with a history of insufflating opioids were randomized into the treatment phase of the study after demonstrating they could adequately distinguish euphoria or "high" (measured as drug liking) between placebo and two different doses of hydrocodone/APAP (the drug discrimination phase).

In the blinded treatment phase, fasted subjects snorted a single dose of five different crushed study drugs every 48 hours, using either 10mg or 20mg of hydrocodone bitartrate based on the lowest dose the subject could adequately distinguish in the drug discrimination phase. Study drugs were administered in a randomized crossover design. The primary study drugs were placebo, Generic hydrocodone/APAP, and AVERSION hydrocodone/APAP. Two active control drugs were used to blind the subjects to the different powder volumes of the primary study drugs and provide information on the impact of powder volume and the AVERSION ingredients on drug liking scores.

Subjects snorted the crushed study drugs using both nostrils over 5 minutes in a design to visually blind the study drugs. The primary endpoint was the subjects' maximum score (Emax) of their drug like/dislike on a 101-point visual analog scale (VAS) at various intervals following administration, with a score of 0 indicating a strong dislike, 100 a strong like and 50 a neutral response. Secondary endpoints measured on a 101-point VAS scale included the minimum score (Emin) of their drug like/dislike, the subjects' willingness to take drug again, assessment of overall drug like/dislike, and assessment of drug high. Subjects also responded to a 6-point Likert scale for nasopharyngeal and facial side effects associated with the AVERSION technology. Pharmacokinetic blood samples were also collected and analyzed for each subject.

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 AVERSION® and IMPEDE® technologies. 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 incorporates 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 our expectations of the results of Study 301, whether we can identify variables that could have impacted the results of Study 301 and wether those variables will be determined acceptable by the FDA to conduct an additional intranasal abuse liability study on our AVERSION hydrocodone/APAP, whether we will conduct an additional intranasal abuse liability study on our AVERSION hydrocodone/APAP product and whether the results of such study will support a claim of intranasal abuse deterrence, our plans and expectations relating to our AVERSION hydrocodone/APAP or other AVERSION Technology product candidates, the expected timing of submission of the NDA for AVERSION hydrocodone/APAP to the FDA, our expectations of the side affects associated with AVERSION hydorcodone/APAP or other AVERSION Technology product candidates, the results of our meetings or discussions with the FDA relating to the FDA's advice concerning our AVERSION hydrocodone/APAP product, our ability to file for and obtain FDA approval of the NDA for AVERSION hydrocodone/APAP, our ability to obtain labeling for AVERSION hydrocodone/APAP containing the results of an intranasal abuse liability study, our and our licensee's ability to successfully launch and commercialize our products and technologies including AVERSION oxycodone and NEXAFED Tablets, our and our licensee's ability to obtain necessary regulatory approvals and commercialize products utilizing our technologies and 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 other product candidates, our exposure to product liability and other lawsuits in connection with the commercialization of our products, the increased 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, and the ability of our patents to protect our products from generic competition, our ability to protect and enforce our patent rights in any paragraph IV patent infringement litigation, and 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 to meet over-the-counter, or 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 and how it may evaluate the results of these studies or 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, whether our product candidates will ultimately deter abuse in commercial settings and whether 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," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," Predicts," "potential," "indicates" 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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