August 26, 2013

Acura Pharmaceuticals Announces Top-Line Results of a Clinical Study Assessing Abuse Liability

PALATINE, IL -- (Marketwired) -- 08/26/13 -- Acura Pharmaceuticals, Inc. (NASDAQ: ACUR) today announced top-line results from Study AP-ADF-301 (Study 301), a phase II clinical study in 40 recreational drug abusers assessing the abuse liability of snorting a crushed hydrocodone bitartrate with acetaminophen tablet formulated with Acura's abuse deterrent AVERSION technology (AVERSION H&A).

The results for AVERSION H&A in Study 301 were consistent in certain respects with the results of a similar study for another AVERSION product containing oxycodone hydrochloride, which has been approved by the US Food and Drug Administration (FDA). Study 301's primary endpoint indicated AVERSION H&A had slightly lower numeric mean maximum drug liking (Emax: 72.1) compared to an equivalent dose of a generic hydrocodone/acetaminophen tablet (Generic H&A: Emax: 75.6) currently on the market, however these results were not statistically significant ($p > 0.025$).

The secondary endpoints demonstrated the effects of the AVERSION ingredients on drug snorting. AVERSION H&A's mean minimum liking (Emin: 40.2) was less than Generic H&A (Emin: 50.4) (the difference being statistically significant at $p=0.0003$). The mean minimum drug liking for AVERSION H&A and the placebo control were 40.2 and 48.8, respectively (the difference being statistically significant at $p=0.0042$). A score below 50 indicates a subject disliked the drug they were taking at some point during the treatment (a score of 50 means neither like or dislike), and a score greater than 50 indicates they liked the drug they were taking.

The mean minimum liking results correlated closely the Overall Drug Liking score (ODL) and Take Drug Again assessment (TDA). ODL assessed the subject like or dislike for the drug experience 12 hours after taking the dose. The ODL for AVERSION H&A (52.7) was lower than Generic H&A (71.0) (the difference being statistically significant at $p=0.0001$) with a score of 50 indicating a neither a like or dislike. TDA assessed a subject's willingness to take the drug again assessed 12 hours after taking the dose. The TDA for AVERSION H&A (45.1) was lower than Generic H&A (71.0) (the difference being statistically significant at $p=0.0001$) with the AVERSION H&A score below 50 indicating an unwillingness to take the drug again.

There were no serious adverse events reported for AVERSION H&A. There was no sequence effect identified in the study but a carryover effect between the 5 study crossover periods was identified for the Emax measure but not the Emin measure. This effect is being further evaluated.

Acura intends to further evaluate the data from this study and plans to meet with the FDA to discuss these results. AVERSION H&A tablets contain a unique composition of inactive ingredients intended to deter common methods of prescription drug abuse such as snorting. Given the absence of statistical significance in Study 301s primary endpoint relating to maximum drug liking, the timeline for submission of a New Drug Application (NDA) for AVERSION H&A is expected to be delayed. The revised projected timeline for submission of the NDA for Aversion H&A will be determined following our meeting with the FDA. Although we do not expect the need to conduct additional nasal abuse like/dislike studies for AVERSION H&A, this will not be confirmed until our meeting with the FDA to discuss the Study 301 results.

Some of the significant differences observed in Study 301 compared to the results seen for the AVERSION oxycodone hydrochloride product study include, but are not limited to: (a) mean maximum drug liking scores for the active comparator (i.e. Generic H&A) were significantly lower, (b) the time to mean minimum drug liking for AVERSION H&A was longer, (c) almost all AVERSION H&A subjects snorted the entire dose compared to only 48% for AVERSION oxycodone hydrochloride, and (d) AVERSION oxycodone hydrochloride achieved a statistically significant reduction in mean maximum drug liking scores before adjusting for an observed sequence effect.

The Company will host a conference call to discuss the results on ***Tuesday, August 27 at 8:30 a.m. ET.*** To participate in the live conference call, please ***dial 888-539-3696*** (U.S. and Canada) five to ten minutes prior to the start of the call. The participant passcode is ***8585569***.

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 H&A 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 H&A, and AVERSION H&A. 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 OXECTA® (oxycodone HCl 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, our expectations relating to AVERSION H&A or other AVERSION Technology product candidates, our expectations relating to suitability of the Study 301 results for filing with the FDA and the absence of need to conduct additional nasal abuse like/dislike studies for AVERSION H&A, the expected timing of submission of the NDA for AVERSION H&A to the FDA, our expectations of the side effects associated with AVERSION H&A or other AVERSION Technology product candidates, the results of our meeting with the FDA to discuss the results of Study 301, our ability to file for and obtain FDA approval of the NDA for AVERSION H&A, our and our licensee's ability to successfully launch and commercialize our products and technologies including OXECTA Tablets and NEXAFED Tablets, the price discounting that may be offered by Pfizer for OXECTA, 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" 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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