



August 15, 2014

Acura Pharmaceuticals Provides Update on FDA Discussions Surrounding Development of Aversion Hydrocodone With Acetaminophen Tablet

PALATINE, IL -- (Marketwired) -- 08/15/14 -- Acura Pharmaceuticals Inc. (NASDAQ: ACUR), announced today preliminary discussions from a meeting held with the U.S. Food and Drug Administration (FDA) regarding the development pathway for Acura's AVERSION® hydrocodone with acetaminophen tablet development candidate, which is intended to provide abuse-deterrent features to address abuse by nasal snorting and injection. In a May 2014 letter to Acura, FDA questioned the relevance of abuse of hydrocodone with acetaminophen products by nasal snorting after reviewing clinical and epidemiology data submitted by Acura.

The FDA continues to question the relevance of abuse of hydrocodone with acetaminophen products by the intranasal route of administration and suggested additional information may help better inform their decision. The FDA indicated in the discussions that Acura may conduct an additional nasal abuse liability study for its AVERSION hydrocodone with acetaminophen product candidate, the outcomes of which may help inform the relevance decision as well as establish a reduction in drug liking, which was not statistically significant in an earlier Acura study (Study AP-ADF-301). The FDA requested further time to deliberate on the issues discussed during the meeting before issuing final meeting minutes.

Acura intends to review its clinical data from Study AP-ADF-301 to determine whether to proceed with an additional clinical study for its AVERSION hydrocodone with acetaminophen product candidate and to further evaluate options to address the issues of intranasal abuse and drug liking raised by the FDA.

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

- 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® 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," "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.

Contact:
for Acura Investor Relations

[Email Contact](#)
847-705-7709

for Acura Media Relations

[Email Contact](#)

Source: Acura Pharmaceuticals, Inc.

News Provided by Acquire Media