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Acura Pharmaceuticals Launches Next Generation Cold Medicine to Aid in the Fight Against Meth

Nexafed(R)'s Abuse-Deterrent Technology Disrupts Conversion of Pseudoephedrine to Dangerous Illegal Drug Methamphetamine Without Compromising Effective Nasal-Congestion Relief

PALATINE, IL -- (Marketwire) -- 12/10/12 -- Acura Pharmaceuticals, Inc. (NASDAQ: ACUR) today announced the launch of Nexafed® [pseudoephedrine hydrochloride (HCl)], a 30 mg immediate-release next generation pseudoephedrine product, combining effective nasal-congestion relief with a unique technology that disrupts the conversion of pseudoephedrine into the dangerous drug, methamphetamine. Nexafed® is now available to national and regional drug wholesalers and will be available to pharmacies soon. This is the second of two products to reach the market that utilize Acura's abuse-deterrent technologies.

"The launch of Nexafed® is a significant milestone for Acura and in the continued fight against meth in the U.S.," said Robert B. Jones, president and chief executive officer of Acura Pharmaceuticals. "Acura is highly committed to addressing the needs of local communities by investing in the development of abuse-deterrent technologies and medicines. It's not about innovating once, but continuing to improve on the technology without compromising efficacy."

Nexafed® delivers the same efficacy as leading pseudoephedrine products. In a clinical study Nexafed® was shown to meet the Food and Drug Administration's (FDA) guidelines for bioequivalence when compared to the leading national brand product.(1) For consumers, confirmation of bioequivalence provides assurance that Nexafed® delivers the same cold and allergy relief they have come to rely on -- but with the added benefit of disrupting possible methamphetamine production.

Pseudoephedrine, a decongestant used in some cold and allergy medicines, is the primary ingredient converted during illegal methamphetamine production. Unlike other cold and allergy pseudoephedrine products, Nexafed® is the only medicine that utilizes Acura's Impede™ technology, a unique polymer matrix that disrupts the extraction and conversion of pseudoephedrine to methamphetamine. If abusers try to extract the pseudoephedrine out of Nexafed® to make methamphetamine, the inactive ingredients in the polymer matrix will form a thick gel to block that extraction and disrupt conversion of pseudoephedrine to methamphetamine.

Laboratory tests conducted on Acura's behalf by an independent research organization demonstrated that in the two methods of methamphetamine production that require pseudoephedrine extraction prior to conversion, no pseudoephedrine could be extracted and isolated from Nexafed® using a range of aqueous and organic solvents. In addition, in the direct conversion method, or "one-pot" technique used in home labs, laboratory tests demonstrated that Impede™ technology reduced the yield of methamphetamine from conversion of pseudoephedrine by about half of that derived from the leading national brand product.

"The introduction of cold and allergy products with abuse-deterrent technologies is a significant step forward for communities across the country affected by the debilitating effects of meth production," said Priscilla Lisicich, executive director of Safe St. located in Tacoma, Washington and former co-chair of the National Methamphetamine Training and Technical Assistance Center. "A medicine that deters meth production without compromising efficacy will ensure people have access to the medicines that they need."

Methamphetamine production and abuse is a serious problem that has become increasingly common in communities across the U.S. In 2011, approximately 439,000 Americans ages 12 years and older had abused methamphetamine.(2) The impact of methamphetamine extends beyond those who use and abuse the drug. Methamphetamine production creates increased danger in communities from fire, explosions, exposure to toxic chemicals and crime.

Last year, more than 10,000 clandestine labs were found in the U.S., triggering environmental hazards and requiring expensive and timely cleanup by local governments.(3) In addition to environmental hazards, the economic cost of methamphetamine use in the U.S. -- estimated at \$23.4 billion in 2005 -- is staggering, accounting for the burden of addiction and drug treatment.(4)

"We hope the availability of Nexafed® empowers pharmacists to impact meth abuse at a local level by stocking and recommending the product," said Jones. In a recent market research study, 70 percent of chain and independent pharmacists involved in pharmacy stocking decisions said they were likely to stock or recommend stocking Nexafed® in their pharmacies. These pharmacists further indicated a willingness to recommend Nexafed® to over 50 percent of their customers who seek a

pharmacist's advice in need of a single ingredient nasal decongestant like Nexafed®.

Nexafed® is now available to national and regional drug wholesalers and will be available to pharmacies soon. Acura has priced Nexafed® comparably to name-brand pseudoephedrine products. For more information about Nexafed®, please visit JOIN-FIGHT.COM.

About Nexafed®

Nexafed® [pseudoephedrine hydrochloride (HCl)] is 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. Specifically, the Impede (™) technology forms a thick gel when the tablets are dissolved in solvents typically used in the pseudoephedrine extraction or methamphetamine production processes, trapping the pseudoephedrine or converted methamphetamine to prevent its isolation or purification.

About Acura Pharmaceuticals

Acura Pharmaceuticals, Inc. is a specialty pharmaceutical company dedicated to bringing safe and effective products intended to address medication abuse and misuse to market. As a leader in abuse-deterrent technology, Acura has also successfully developed a prescription drug product that addresses abuse and which is licensed to and marketed by a major pharmaceutical company. Acura is committed to addressing the needs of local communities by investing in ongoing research and development to drive improvement in drug-deterrent 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. 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 statements. Forward-looking statements may include, but are not limited to, the timing of, our ability to successfully launch and commercialize Nexafed® Tablets, 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, the adequacy of the results of the laboratory and clinical studies completed to date, the sufficiency of our development to meet over-the-counter, or OTC, Monograph standards as applicable, adverse safety findings relating to our 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, and whether our Impede™ technology, including our Nexafed® Tablets, 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," "indicated," "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.

References

- (1) Data on file; Acura Pharmaceuticals, Inc., Palatine, IL
- (2) Substance Abuse and Mental Health Services Administration, [Results from the 2011 National Survey on Drug Use and Health: Summary of National Findings](#), NSDUH Series H-44, HHS Publication No. (SMA) 12-4713. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2012.
- (3) Drug Enforcement Administration. [Maps of Methamphetamine Lab Incidents](#).
- (4) The RAND Corporation. [The Economic Costs the Methamphetamine Use in the United States](#), 2005.2009.

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