



September 3, 2013

Research Confirms New Nasal Decongestant Product Is Highly Meth-Resistant Yet Offers Same Effectiveness as Leading Pseudoephedrine Brand

Study Published in American Journal of Drug and Alcohol Abuse Shows NEXAFED(R) Significantly Disrupts the Extraction and Conversion of Pseudoephedrine to Methamphetamine, While Demonstrating Bioequivalence to the Leading Pseudoephedrine Brand

PALATINE, IL -- (Marketwired) -- 09/03/13 -- Acura Pharmaceuticals, Inc. (NASDAQ: ACUR) today announced a study, published in the September issue of the *American Journal of Drug and Alcohol Abuse*, that validates the ability of NEXAFED[®] to uniquely disrupt the extraction and conversion of pseudoephedrine (PSE) into methamphetamine (meth) and confirms that NEXAFED delivers the same efficacy compared to other similar pseudoephedrine (PSE) products. The article, "[The Advent of New Pseudoephedrine Product to Combat Methamphetamine Abuse](#)," also affirms the benefits of widespread adoption of tamper-resistant PSE products that offer effective therapeutic relief for nasal congestion.

"NEXAFED[®], with its unique IMPEDE[®] technology, was specifically developed to address two key issues: to treat nasal congestion and to fight illicit meth production," said Albert W. Brzeczko, PhD, lead study author and Vice President, Technical Affairs with Acura Pharmaceuticals. "With the outcome of this research, we are pleased to confirm that it is effective on both fronts."

The study measured the ability of NEXAFED's IMPEDE technology to disrupt the extraction and conversion of PSE by meth cooks using common clandestine meth lab processes. When simulating large scale manufacturing to extract and convert pure PSE into meth, researchers found that NEXAFED's IMPEDE technology yielded no measurable PSE extraction, representing a significant impediment compared to the control Sudafed[®] tablets (Sudafed[®] is a registered trademark and product of Johnson & Johnson). When tested under the "one-pot" conversion method, the study indicated that current IMPEDE technology tablets had an approximate 38 percent yield, nearly half the average meth recovered compared to the control. Currently, Acura Pharmaceuticals is improving its present formulation and developing new IMPEDE 2.0 technology, which yielded no measurable amount of meth with the one-pot conversion method in initial testing of a prototype formulation by an outside laboratory.

To test the therapeutic equivalence of NEXAFED, Acura Pharmaceuticals and an independent research laboratory conducted an open label, randomized crossover study of 30 healthy adults. Participants were given a single dose of two 30mg tablets of either NEXAFED or Sudafed[®] on two separate occasions, and provided blood samples over a 24-hour period to chart how the pseudoephedrine was processed in the blood stream. The data confirmed there is no significant difference in the rate and extent of drug absorption between the two groups. We believe this will give pharmacists confidence to recommend NEXAFED knowing their patients will get the same nasal congestion relief they've come to expect from older PSE products.

"The advent of new pseudoephedrine products with deterrent technologies, such as NEXAFED[®], provides a significant value to cold and allergy sufferers, pharmacists and law enforcement officials in the fight against meth abuse," said Robert B. Jones, president and chief executive officer of Acura Pharmaceuticals. "We are very proud that NEXAFED, available in independent and chain drug and grocery stores nationwide, provides effective relief from cold and allergy symptoms while at the same time helping keep our communities safer."

For more information about NEXAFED, which is currently distributed through national and regional drug wholesalers to chain and independent drugstores nationwide, and for updates on the rollout of the new IMPEDE 2.0 technology, visit [JOIN-FIGHT.COM](#).

About NEXAFED[®]

NEXAFED[®] [pseudoephedrine hydrochloride] 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. 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 resist its isolation or purification.

About Acura Pharmaceuticals, Inc.

Acura Pharmaceuticals, Inc. is a specialty pharmaceutical company dedicated to bringing to market safe and effective products intended to address medication abuse and misuse. As a leader in abuse-deterrent technology, Acura Pharmaceuticals has successfully developed a prescription drug product that addresses abuse and which is licensed to and marketed by a major pharmaceutical company. Acura Pharmaceuticals is committed to addressing the needs of local communities by investing in ongoing research and development to drive improvement in abuse-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 develop and launch our next generation 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, including whether NEXAFED will prove resistant to methamphetamine conversion methods that may be utilized in the future by clandestine methamphetamine laboratories. 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.

Contacts

Investor Relations:

Pete Clemens

Acura Pharmaceuticals

[Email Contact](#)

847-705-7709

Media Relations:

Kaitlin Bowen

Spectrum

[Email Contact](#)

202-955-6222

Source: Acura Pharmaceuticals, Inc.

News Provided by Acquire Media