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Acura Pharmaceuticals Announces Successful Bioequivalent Study for NEXAFED

PALATINE, IL -- (Marketwire) -- 11/20/12 -- Acura Pharmaceuticals, Inc. (NASDAQ: ACUR), a specialty pharmaceutical company developing products intended to address medication abuse and misuse, announced today topline results from a clinical study that demonstrates Acura's NEXAFED (pseudoephedrine hydrochloride) is bioequivalent to the leading national brand product. The study was a Phase 1 pharmacokinetic study in 30 healthy adult subjects to confirm that changes made to the formulation for NEXAFED to improve manufacturability in support of a national launch will continue to provide effective relief of nasal congestion expected by pharmacists and consumers.

NEXAFED is a 30 mg immediate-release next generation pseudoephedrine tablet, which combines effective nasal-congestion relief with Acura's unique IMPEDE technology that disrupts the conversion of pseudoephedrine into the dangerous drug, methamphetamine.

"It is important that our IMPEDE technology used in NEXAFED does not compromise the effectiveness of the active ingredient, and the results of our clinical study demonstrate this," said Bob Jones, President and Chief Executive Officer of Acura Pharmaceuticals. "We remain on track for a national launch of NEXAFED later this year."

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. In June 2011, the U.S. Food and Drug Administration approved OXECTA® which incorporates the AVERSION® technology. The Company has a development pipeline of additional AVERSION® technology products including other opioids and its IMPEDE™ technology for pseudoephedrine hydrochloride products.

The trademark OXECTA® is owned by Pfizer Inc.

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, and 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, 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," "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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