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Acura Pharmaceuticals Initiates Clinical Study of Meth-Resistant Nexafed(R) Extended-Release Formulations

Products Employ Improved Impede(R) 2.0 Technology

PALATINE, IL -- (Marketwired) -- 02/16/15 --

Acura Pharmaceuticals, Inc. (NASDAQ: ACUR), today announced the initiation of treatment in a pilot clinical study of two experimental formulations of NEXAFED (pseudoephedrine HCl) extended-release tablets employing Acura's 2nd generation methamphetamine resistant technology, IMPEDE 2.0. The study in fasted, healthy subjects will measure the systemic absorption of the active ingredient, pseudoephedrine, from two experimental NEXAFED extended-release formulations compared to an FDA-approved 12-hour extended-release reference product. The objective of the study is to characterize the bioavailability profile of the NEXAFED formulations for possible adjustment before pivotal human pharmacokinetic testing is undertaken.

The experimental NEXAFED extended-release formulations include Acura's enhanced IMPEDE 2.0 technology that delivers superior meth-resistance in the direct conversion, or "one-pot", methamphetamine conversion process compared to IMPEDE 1.0 and other meth-resistant technologies in the market. IMPEDE 2.0 in the extended-release formulation has demonstrated, in direct conversion tests performed by an independent, international pharmaceutical services company, the ability to reduce meth-yields, on average, by 75% compared to Sudafed® Tablets.

Meth Production from 3 grams of Pseudoephedrine HCl in the Direct Conversion "One-Pot" Method

Product	Meth-Resistant Technology	Average Meth Recovery[1]	Average Purity[2]
Sudafed® 30mg Tablets	None	67%	62%
Nexafed® 30mg Tablets	Impede® 1.0	38%	65%
Zephrex-D® 30mg Pills	Tarex®	28%	51%
Nexafed® 120mg Extended-Release Tablets[3]	Impede® 2.0	17%[3]	34%[3]

[1] Total methamphetamine HCl (meth) recovered from 3 grams of pseudoephedrine tablets divided by the maximum theoretical yield of 2.7 grams.

[2] Total methamphetamine HCl recovered from 3 grams of pseudoephedrine tablets divided by the total weight of powder recovered.

[3] Final methamphetamine HCl yields and purity will be dependent on final formulation selection.

Dr. Al Brzeczko, Acura's Vice President of Technical Affairs, commented, "These extended-release NEXAFED formulations have met our expectations in the laboratory with respect to both rate of in-vitro release as well as meth-resistance performance. This study will provide us with valuable insights into the performance of the products in humans and guide our future development efforts toward a filing with the FDA."

"Advancing these extended-release formulations is critical to our strategy to develop a full-line of meth-resistant pseudoephedrine products", said Bob Jones, Acura's President and CEO. "Extended-release products will complement our current NEXAFED and NEXAFED Sinus offerings and position us to sell into the largest segments of the pseudoephedrine category."

About NEXAFED and IMPEDE

NEXAFED is Acura's line of next generation pseudoephedrine products built around IMPEDE technology, that uses a unique polymer matrix to disrupt the conversion of pseudoephedrine into the dangerous drug, methamphetamine. Specifically, IMPEDE tablets 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. Acura commercially launched NEXAFED (pseudoephedrine HCl) 30mg tablets in December 2012 and the only meth-resistant combination pseudoephedrine product, NEXAFED Sinus Pressure + Pain (pseudoephedrine HCl/acetaminophen) 30/325mg tablets in February 2015. The NEXAFED line is available at national and regional drug, grocery and mass merchandiser pharmacies. NEXAFED delivers the same efficacy and is priced comparably to similar branded

pseudoephedrine products. For more information about NEXAFED, please visit www.nexafed.com.

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 LIMITX™, AVERSION® and IMPEDE® Technologies. LIMITX contains ingredients that are intended to reduce or limit the rate or extent of opioid release when multiple tablets are ingested. AVERSION contains polymers that cause the drug to gel when dissolved; it also contains compounds that irritate the nasal passages if the product is snorted. IMPEDE is designed to disrupt the processing of pseudoephedrine from tablets into methamphetamine.

In June 2011, the U.S. Food and Drug Administration approved Oxaydo™ (oxycodone HCl immediate-release tablets) which incorporates the AVERSION Technology. On January 7, 2015, we entered into a Collaboration and License Agreement with Egalet US, Inc. and Egalet Ltd., each a subsidiary of Egalet Corporation, pursuant to which we exclusively licensed to Egalet worldwide rights to manufacture and commercialize Oxaydo. The Company has a development pipeline of additional AVERSION Technology products containing other opioids.

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. Forwarding-looking statements may include, but are not limited to, the meth resistant benefits of our IMPEDE 2.0 technology, the results of the pilot clinical study for our experimental formulations of NEXAFED using our IMPEDE 2.0 technology, whether such formulations will lead to commercial products, whether or when we are able to obtain FDA approval of these product candidates, whether we will be able to promote the features of our meth-resistant technology, whether our product candidates utilizing our IMPEDE 2.0 technology will disrupt the processing of pseudoephedrine into methamphetamine, and whether competitors will develop and commercialize products using alternative meth-resistant technologies that are more effective than our IMPEDE 2.0 technology. 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 statements.

Sudafed is a registered trademark of Johnson and Johnson Corp.
Zephrex-D is a registered trademark of Westport Pharmaceuticals LLC
Tarex is a registered trademark of Highland Pharmaceuticals LLC

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