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Acura Pharmaceuticals Announces Settlement of Patent Litigation With Ranbaxy Inc.

PALATINE, IL -- (Marketwired) -- 05/08/14 -- Acura Pharmaceuticals, Inc. (NASDAQ: ACUR), a specialty pharmaceutical company developing products intended to address medication abuse and misuse, announced today that it has entered into a Settlement Agreement with Ranbaxy Inc. to dismiss, without prejudice, its patent infringement action pending against Ranbaxy in the United States District Court for the District of Delaware. In the suit, Acura alleges that a generic of Acura's AVERSION® oxycodone product, previously marketed by Pfizer Inc. under its brand name OXECTA®, for which Ranbaxy is seeking approval to market in the United States pursuant to an Abbreviated New Drug Application (ANDA) filing with the U.S. Food and Drug Administration (FDA) infringes U.S. patents owned by Acura.

The Settlement Agreement provides that Ranbaxy's current product that is the subject of its ANDA does not infringe Acura's Orange Book listed patents with the FDA. Acura has not provided Ranbaxy with a license to Acura's patents and Acura may recommence patent infringement litigation against Ranbaxy if Ranbaxy changes the formulation of its generic to the AVERSION® oxycodone product.

Acura's President and CEO, Bob Jones said, "Based on the current formulation approach of Ranbaxy's generic product, we determined that settlement of the suit was advisable. The FDA now must determine if Ranbaxy's product has abuse deterrent features comparable to our AVERSION® oxycodone product or can match the our AVERSION® oxycodone product label."

Background on the litigations settled

On September 20, 2012, we announced that we had received a Paragraph IV Certification notice from a generic sponsor of an ANDA for a generic OXECTA® product. Since such date, we have received similar Paragraph IV Certification notices from four other generic pharmaceutical companies that have filed ANDAs for generic AVERSION® oxycodone products. As a result, on October 31, 2012, we initiated suit against each of Watson Laboratories, Inc. -- Florida (Watson), Par Pharmaceutical, Inc., Impax Laboratories, Inc. and Sandoz Inc. in the United States District Court for the District of Delaware. On April 29, 2013, we initiated suit against Ranbaxy Pharmaceuticals in the United States District Court for the District of Delaware. In each such litigation, we have alleged infringement of our U.S. Patent No. 7,510,726 listed in the FDA's Orange Book, and having an expiration date in November 2023.

On January 2, 2013, our motion to dismiss the litigation against Watson on the grounds that Watson had amended its ANDA from a Paragraph IV Certification to a Paragraph III Certification, which indicated its intent not to market its generic Oxecta® product in advance of our patent expiring, was accepted by the Court. On October 9, 2013 we announced Settlement Agreements with each of Par Pharmaceutical and Impax Laboratories. The Settlement Agreement with Ranbaxy does not affect the status of Acura's separate AVERSION® oxycodone patent litigation against Sandoz Inc. pending in the U.S. District Court for the District of Delaware.

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 OXECTA® (oxycodone HCl tablets) which incorporates the AVERSION® technology. The Company has a development pipeline of additional AVERSION® technology products containing other opioids.

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, that the U.S District Court does not approve the Stipulation of Dismissal of the litigation with Ranbaxy, that the U.S. Federal Trade Commission or the U.S. Department of Justice challenge the enforceability of the Settlement Agreement or that private plaintiffs challenge the Settlement Agreement, whether or not additional third parties may seek to market generic versions of our AVERSION® oxycodone product and the results of our pending litigation or future litigation we may file to defend and/or assert our patents against such companies, our ability to enter into a license agreement for our Aversion oxycodone product, our and our licensee's ability to successfully launch and commercialize our products and technologies including our Aversion oxycodone and NEXAFED® Tablets, the price discounting that may be offered by our licensee for Aversion oxycodone, our or our licensee's ability to obtain commercial supplies of Aversion oxycodone from a third party contract manufacturer, our and our licensee's ability to obtain necessary regulatory approvals and commercialize products utilizing our technologies and the market acceptance of and competitive environment for any of our products, the willingness of wholesalers and pharmacies to stock NEXAFED® Tablets, expectations regarding the terms and payments under any license agreement for our products, 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, and the ability of our patents to protect our products from generic competition, our ability to protect and enforce our patent rights in any paragraph IV patent infringement litigation, and 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 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 and how it may evaluate the results of these studies or 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, whether our 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.

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