



October 18, 2016

## **KemPharm Announces Licensing Agreement with Acura Pharmaceuticals for Aversion (R) Abuse-Deterrent Technology**

### **Agreement focused on KemPharm's current and in-development IR Opioid Pipeline**

CORALVILLE, IA and PALATINE, IL -- (Marketwired) -- 10/18/16 --

KemPharm, Inc. (NASDAQ: KMPH), a clinical-stage specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs, and Acura Pharmaceuticals, Inc. (NASDAQ: ACUR) today announced that they have entered into a License Agreement (the "Agreement") whereby Acura will provide its proprietary Aversion® Technology to KemPharm to use with its current and in-development immediate release (IR) opioid product candidates. Aversion® Technology is a patented composition of commonly used active and inactive pharmaceutical ingredients providing abuse deterrent features (ADF) and benefits for orally administered pharmaceutical drug products.

The Agreement provided for an upfront cash payment of \$3.5 million to Acura at execution and grants KemPharm development and commercialization rights for up to three IR product candidates containing two of KemPharm's opioid prodrugs. Additional payments are provided in the Agreement should KemPharm exercise its option to use Acura's Aversion® Technology with more than the three products. Acura is eligible to receive a royalty at a low single-digit rate based on commercial sales by KemPharm of all products developed under the Agreement. KemPharm will solely own the intellectual property resulting from any new product development.

"Acura's Aversion® Technology, an FDA-approved aversive ADF approach without a food effect, and KP201/IR, our priority lead product candidate, together offer significant potential benefits," stated Travis C. Mickle, Ph.D., President and Chief Executive Officer of KemPharm. "We believe today's Agreement will help us bridge the regulatory approval process between current abuse deterrence products and the ability of our new molecular entity prodrugs to demonstrate their ADF properties."

"Based on the strength of our existing data, as well as what we view to be favorable developmental, regulatory and market conditions, we expect this agreement with Acura to allow us to bring a unique prodrug product with the addition of demonstrated aversive barriers to the market in the near term," Mickle continued. "Access to this technology was contemplated in the guidance for timelines we recently provided for KP201/IR."

"We are excited to partner with KemPharm who, like us, is committed to address the problem of prescription opioid abuse," said Bob Jones, President and CEO of Acura. "We believe KemPharm shares our objective of aggressively developing and bringing to the healthcare community new abuse deterrent IR opioid analgesics to treat pain."

#### **About KemPharm**

KemPharm is a clinical-stage specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs to treat serious medical conditions through its Ligand Activated Therapy (LAT) platform technology. KemPharm utilizes its LAT platform technology to generate improved prodrug versions of FDA-approved drugs in the high need areas of pain, ADHD and other CNS (central nervous system) disorders

#### **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. Acura markets NEXAFED® and NEXAFED® Sinus, which are pseudoephedrine containing products that utilize the IMPEDE Technology.

#### **Caution Concerning Forward Looking Statements KemPharm's Forward Looking Statements**

This press release may contain forward-looking statements made in reliance upon the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include all statements that do not relate solely to historical or current facts, and can be identified by the use of words such as "may," "will," "expect," "project," "estimate," "anticipate," "plan," "believe," "potential," "should," "continue" or the negative versions of those words or other comparable words. These forward-looking statements include statements regarding the potential development of any product candidates under the Agreement, the expected features and characteristics of KemPharm's current and in-development opioid product candidates, including those potentially developed under the Agreement, and the related development timelines for KP201/IR. These forward-looking statements are not guarantees of future actions or performance. These forward-looking statements are based on information currently available to KemPharm and its current plans or expectations, and are subject to a number of uncertainties and risks that could significantly affect current plans. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors, including, the risks and uncertainties associated with: KemPharm's financial resources and whether they will be sufficient to meet KemPharm's business objectives and operational requirements; results of earlier studies and trials may not be predictive of future clinical trial results; the protection and market exclusivity provided by KemPharm's intellectual property; risks related to the drug discovery and the regulatory approval process; the impact of competitive products and technological changes; and the FDA approval process under the Section 505(b)(2) regulatory pathway, including any timelines for related approval. KemPharm's forward-looking statements also involve assumptions that, if they prove incorrect, would cause its results to differ materially from those expressed or implied by such forward-looking statements. These and other risks concerning KemPharm's business are described in additional detail in KemPharm's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, and KemPharm's other Periodic and Current Reports filed with the Securities and Exchange Commission. KemPharm is under no obligation to (and expressly disclaims any such obligation to) update or alter its forward-looking statements, whether as a result of new information, future events or otherwise.

### ***Acura's 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 Acura's 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:

- | Acura's ability to fund or obtain funding for its continuing operations, including the development of its products utilizing our Limitx™ and Impede® technologies;
- | whether the extent to which products formulated with the Aversion® technology deter abuse or will be determined sufficient by the FDA to support approval or labeling describing abuse deterrent features;
- | Acura's and its licensee's ability to obtain necessary regulatory approvals, successfully launch and commercialize products utilizing its technologies;
- | the market acceptance of, timing of commercial launch and competitive environment for any of Acura's products or products utilizing its technologies;
- | Acura's exposure to product liability and other lawsuits in connection with the commercialization of products utilizing its technologies;
- | the ability to avoid infringement of patents, trademarks and other proprietary rights of third parties;
- | the ability of Acura's patents to protect its products from generic competition and its ability to protect and enforce its patent rights in any paragraph IV patent infringement litigation;
- | the ability to fulfill the FDA requirements for approving Acura's product candidates or products utilizing its technologies 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 its product candidates and the sufficiency of its development process to meet over-the-counter ("OTC") Monograph standards, as applicable;
- | changes in regulatory requirements;
- | adverse safety findings relating to Acura's commercialized products or product candidates in development;
- | whether the FDA will agree with Acura's analysis of its clinical and laboratory studies;
- | whether further studies of Acura's product candidates will be required to support FDA approval;
- | whether or when Acura is able to obtain FDA approval of labeling for its product candidates for the proposed indications and will be able to promote the features of its abuse discouraging technologies; and

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 Acura's 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. Many of these risks are discussed in greater detail in Acura's filings with the Securities and Exchange Commission. Unless required by law, Acura undertakes no obligation to update or revise any forward-looking statements to reflect new information or future events or developments. Accordingly, you should not

assume that Acura's silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements.

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