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# Recro Pharma Provides Pipeline Update

*IV Meloxicam Advancing to Phase III; Pivotal Trials Expected to Commence in First Quarter 2016*

*Company Shifts Focus of Dex-IN to Peri-Procedural Pain Indication*

MALVERN, Pa., Oct. 26, 2015 (GLOBE NEWSWIRE) -- Recro Pharma, Inc. (Nasdaq:REPH), a revenue generating specialty pharmaceutical company developing multiple non-opioid therapeutics for the treatment of acute pain, today provided a clinical and regulatory update on its pipeline candidates. In the first quarter of 2016, the Company intends to initiate a pivotal Phase III clinical development program with IV meloxicam, a long-acting, preferential COX-2 inhibitor, for the treatment of moderate to severe acute post operative pain. For Dex-IN, Recro's intranasal formulation of the selective alpha-2 agonist analgesic, dexmedetomidine, the Company plans to continue to study Dex-IN in painful conditions with a focus on the treatment of peri-procedural pain.

"The decision to advance IV meloxicam into Phase III is an important milestone for Recro and we are excited about the opportunity this candidate represents as a new option for moderate to severe pain in the acute, post operative setting," said Gerri Henwood, Recro Pharma's President and Chief Executive Officer. "Following the successful submission and review of additional FDA requested clinical and nonclinical information and the availability of new clinical drug supply, we expect to initiate the Phase III trials during the first quarter of 2016."

Ms. Henwood continued: "Following our recent discussion with the FDA, we believe the Dex-IN product profile is better suited for peri-procedural pain rather than the post op setting evaluated in our Phase II trial. We are working to design an appropriate Phase II program to evaluate Dex-IN in this patient population. We believe this approach provides the best path forward for this candidate, and we look forward to providing future updates as we progress."

## **IV Meloxicam for the Treatment of Moderate to Severe Acute Pain**

Recro recently met with the U.S. Food and Drug Administration (FDA) to obtain feedback for its proposed IV meloxicam Phase III clinical development program. Based on feedback from the FDA, the Company intends to initiate a Phase III program with IV meloxicam. Recro expects that the Phase III program will include two pivotal clinical trials, as well as other trials. We expect to enroll a total of approximately 1,300 patients in all these trials. One pivotal clinical trial will be designed to demonstrate pain relief over a 48-hour period in a hard tissue, post op pain model, and the other pivotal trial will be designed to demonstrate pain relief over a 24-hour period in a soft tissue, post op pain model. Recro expects to commence the Phase III clinical program during the first quarter of 2016. Recro expects that results from these two pivotal studies, in addition to other clinical trial data and non-clinical data, to be the basis for our New Drug Application (NDA) submission to the FDA for marketing authorization.

The meloxicam clinical program is supported by clinical data from 3 Phase II studies in over 700 patients with acute pain. Results from these studies demonstrated that IV meloxicam has significant analgesic efficacy, including rapid onset of pain relief and time to peak analgesic effect, 18 to 24 hour duration of pain relief and good tolerability.

### **Dex-IN for the Treatment of Acute Pain**

Recro recently met with the FDA to obtain feedback on the Phase II efficacy and safety data, and for its proposed Dex-IN clinical development program. Based on feedback from the FDA regarding Dex-IN's benefit-risk profile, specifically its efficacy and blood pressure effects, which was demonstrated in post op pain, and the subsequent requirements for a post op pain clinical program, the Company believes that such a program is not advisable due to time, cost and associated risks. The Company plans to reevaluate DEX-IN in peri-procedural pain as discussed with FDA. Based on the FDA's feedback, the Company intends to pursue a Phase II dose-ranging program in peri-procedural pain.

The Dex-IN clinical program is supported by clinical data from Recro's clinical studies in which Dex-IN demonstrated significant pain relief compared with placebo.

### **About IV/IM Meloxicam**

Meloxicam is a long-acting, preferential COX-2 inhibitor that possesses anti-inflammatory, analgesic, and antipyretic activities, which are believed to be related to the inhibition of cyclooxygenase (COX) and subsequent reduction in prostaglandin biosynthesis. Meloxicam has been marketed by Boehringer Ingelheim Pharmaceuticals, Inc. since the 1990's as an oral agent, Mobic<sup>®</sup>. IV/IM meloxicam was designed using NanoCrysta<sup>®</sup> platform, a technology that enables enhanced bioavailability of poorly water-soluble drug compounds. Recro acquired IV/IM meloxicam from Alkermes in April 2015.

### **About Dex-IN**

Dex-IN is a proprietary intranasal formulation of dexmedetomidine, or Dex. Dex is a selective alpha-2 adrenergic agonist that has demonstrated sedative, analgesic and anxiolytic properties. The Company is evaluating multiple formulations of Dex to target a range of pain indications.

### **About Recro Pharma, Inc.**

Recro Pharma is a revenue generating specialty pharmaceutical company developing multiple non-opioid therapeutics for the treatment of acute post-operative pain. Recro Pharma is currently developing IV/IM meloxicam, a proprietary, long-acting preferential COX-2 inhibitor, and Dex-IN, a proprietary intranasal formulation of dexmedetomidine, for the treatment of acute pain. Both compounds have successfully completed Phase II clinical trials. As Recro Pharma's product candidates are not in the opioid class of drugs, the Company believes its candidates would avoid many of the side effects associated with commonly prescribed opioid therapeutics, such as addiction, constipation and respiratory distress, while maintaining analgesic effect.

Recro Pharma also owns and operates an 87,000 square foot, DEA-licensed facility that manufactures five commercial products and receives royalties associated with the sales of

these products.

### **Cautionary Statement Regarding Forward Looking Statements**

This press release contains forward-looking statements that involve risks and uncertainties. Such forward looking statements reflect Recro Pharma's expectations about its future performance and opportunities that involve substantial risks and uncertainties. When used herein, the words "anticipate," "believe," "estimate," "upcoming," "plan," "target", "intend" and "expect" and similar expressions, as they relate to Recro Pharma or its management, are intended to identify such forward-looking statements. These forward-looking statements are based on information available to Recro Pharma as of the date of this press release and are subject to a number of risks, uncertainties, and other factors that could cause Recro Pharma's performance to differ materially from those expressed in, or implied by, these forward looking statements. Recro Pharma assumes no obligation to update any such forward-looking statements. Factors that could cause Recro Pharma's actual performance to materially differ from those expressed in the forward-looking statements set forth in this press release include, without limitation: results and timing of the clinical trials of IV/IM meloxicam and Dex-IN; the ability to obtain and maintain regulatory approval of IV/IM meloxicam and Dex-IN, and the labeling under any such approval; regulatory developments in the United States and foreign countries; the Company's ability to raise future financing for continued development; the performance of third-party suppliers and manufacturers; the Company's ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection; the successful commercialization of IV/IM meloxicam and Dex-IN; In addition, the forward looking statements in this press release should be considered together with the risks and uncertainties that may affect Recro Pharma's business and future results included in Recro Pharma's filings with the Securities and Exchange Commission at [www.sec.gov](http://www.sec.gov). Recro Pharma assumes no obligation to update any such forward looking statements.

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