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# Recro Pharma Announces Positive Top-Line Results for Phase II Clinical Trial of Dex-IN

## Company Plans to Meet With FDA to Discuss Phase III Clinical Program

MALVERN, Pa., July 17, 2015 (GLOBE NEWSWIRE) -- Recro Pharma, Inc. (Nasdaq:REPH), a revenue generating specialty pharmaceutical company developing multiple non-opioid therapeutics for the treatment of acute post operative pain, today announced positive efficacy results in the Phase II clinical trial for Dex-IN, a proprietary intranasal formulation of dexmedetomidine, for the treatment of acute pain in adult patients undergoing bunionectomy surgery. Dex-IN met the primary endpoint of the clinical trial in demonstrating significant pain relief compared with placebo over 48 hours. The Company plans to meet with the FDA to discuss the Company's Phase III plans and determine what, if any, additional information will be required in association with the Phase III clinical program for Dex-IN.

"The positive top line results support the potential of Dex-IN, a non-opioid alternative, to treat acute post operative pain," said Gerri Henwood, Recro Pharma's President and Chief Executive Officer. "We look forward to discussing these Phase II results with the FDA and progressing into pivotal Phase III clinical trials."

The Phase II trial was a randomized, multicenter, double-blind, placebo-controlled study to evaluate the efficacy and safety of Recro Pharma's proprietary intranasal formulation of dexmedetomidine, Dex-IN, in adult patients undergoing bunionectomy surgery, initiating dosing of study medication on Post Op Day 1. Patients who met the eligibility criteria were randomized to either a 50µg dose of Dex-IN or a placebo intranasal dose given every 6 hours. Following the beginning of treatment, patients remained under observation for 48 hours at study centers. Patients were followed for 7 days after the initial dose of study medication. There was an oral opioid rescue treatment available to patients in either treatment group, if required, to provide adequate pain relief. A total of 168 patients were randomized and received study medication in the clinical trial, 84 patients in each treatment group. Seven patients discontinued the study early, six for lack of efficacy (three in each treatment group) and one for a serious adverse event of hypotension.

The primary efficacy endpoint of the trial was the summed pain intensity difference over 48 hours, SPID48, starting on Post Op Day 1. Additional efficacy endpoints included use of opioid rescue medication, SPIDs over various time intervals, as well as other standard efficacy analyses. The most common adverse events observed in the study were blood pressure decrease / hypotension, nausea (similar incidences to placebo), nasal discomfort and headache. An adverse event of bradycardia was reported in 3 subjects in the Dex-IN

treatment group.

Bunionectomy surgery generally involves an incision in the top or side of the big toe joint and the removal or realignment of soft tissue and bone. This is done to relieve pain and restore normal alignment to the joint. Bunionectomy surgery typically results in intense post operative pain. In the past, drugs that have demonstrated analgesic effectiveness following bunionectomy surgery have frequently translated that analgesic success into other post operative procedures that result in moderate to severe, acute pain.

### **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, Phase III-ready, long-acting preferential COX-2 inhibitor, and Dex-IN, a proprietary intranasal formulation of dexmedetomidine currently being tested in Phase II, for the treatment of acute post operative pain. 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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