

# Recro Pharma Presents Clinical Data at PAINWeek 2016

## Poster Highlights Efficacy and Safety of IV Meloxicam in Subjects with Moderate to Severe Pain Following Bunionectomy

MALVERN, Pa., Sept. 07, 2016 (GLOBE NEWSWIRE) -- Recro Pharma, Inc. ("Recro" or the "Company") (Nasdaq:REPH), a revenue generating specialty pharmaceutical company focused on products for hospital and ambulatory care settings, currently developing non-opioid products for the treatment of serious acute pain, today announced a poster presentation at this year's PAINWeek®, the National Conference on Pain for Frontline Practitioners, taking place in Las Vegas, NV from September 6 – 10, 2016. The poster presentation highlights data from a clinical trial evaluating the efficacy and safety of intravenous (IV) meloxicam (N1539) in subjects with moderate to severe pain following bunionectomy from a phase II study.

The poster will be available for viewing at the Gracia 7 section at the Cosmopolitan of Las Vegas during the meeting. Company representatives will be available to discuss the poster during an author-attended session on Thursday, September 8, from 6:30 pm – 8:30 pm PDT.

"In the results presented at this year's PAINWeek meeting, IV meloxicam was shown to demonstrate a significant reduction in post-operative pain reduction following bunionectomy surgery, a highly relevant pain model, with a favorable tolerability profile," said Stewart McCallum, MD, Recro Pharma's Chief Medical Officer. "These phase II results validate Recro Pharma's ongoing Phase III clinical program and highlight IV meloxicam's therapeutic potential as a promising non-opioid option for patients with acute postoperative pain."

These data are being presented in support of the Company's lead product, IV meloxicam, a proprietary, preferential, long-acting COX-2 inhibitor that has successfully completed the first of three pivotal Phase III trials, examining efficacy following bunionectomy surgery, as well as multiple Phase II trials.

Details for the poster presentation at PAINWeek are as follows:

**Title:** An Evaluation of the Safety and Efficacy of N1539, a Novel Intravenous Formulation of NanoCrystalMeloxicam, Administered By IV Push in Subjects with Moderate to Severe Pain Following Bunionectomy

**Poster Number:** 83

**Summary:** The poster describes the phase II, single-center, randomized, double-blind, placebo-controlled study in male and female subjects, age 18-75 years in otherwise good health, undergoing simple unilateral bunionectomy. The primary efficacy objective was to evaluate the effect size of N1539 using the summed PI difference from Hour 0 to 48 (SPID<sub>48</sub>) after dosing. This phase II study supports the safety and tolerability of N1539 at a

60 or 30 mg IV dose administered once daily as a bolus over 15-30 seconds. Additionally, the study demonstrated superior efficacy of N1539 at 60 and 30 mg dose levels versus placebo at all evaluated SPID intervals (6, 12, 24, 48, 12-48, and 24-48 hours). The efficacy analysis was favorable for both N1539 dose levels compared to placebo with estimated effect size ranging from 0.52 to 1.01 per observed SPID<sub>48</sub>, and statistically significant differences in SPID intervals throughout the study. As no incremental benefit was identified using a higher treatment dose, this study supports the use of N1539 30 mg administered IV once daily in post-operative settings where patients are expected to have moderate to severe pain.

A downloadable copy of the poster can be accessed by visiting the "Investors" section of the [Recro Pharma website](#) and by clicking "Presentations."

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

Recro Pharma is a revenue generating specialty pharmaceutical company focused on products for hospital and ambulatory care settings, currently developing non-opioid products for the treatment of serious acute pain. Recro Pharma is currently developing IV meloxicam, a proprietary, long-acting preferential COX-2 inhibitor for treatment of acute postoperative pain, which has completed four successful Phase II clinical trials in postoperative pain conditions and has reported positive results from its first pivotal Phase III clinical trial in patients following bunionectomy surgery. An additional development candidate, Dex-IN, a proprietary intranasal formulation of dexmedetomidine, is being pursued for the treatment of peri-procedural pain, and has had a past successful Phase II trial in bunionectomy. 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 a 97,000 square foot, DEA-licensed facility that manufactures five commercial products and receives manufacturing revenues and royalties associated with the sales of these products.

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

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about the Company's strategy, future operations, clinical development plans and other statements containing the words "anticipate," "believe," "estimate," "upcoming," "plan," "target," "intend," "expect" and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: results and timing of the clinical trials of IV meloxicam and Dex-IN; unfavorable new clinical data and additional analyses of existing clinical data; whether results of early clinical trials will be indicative of the results of future trials and whether interim results from a clinical trial will be predictive of the final results of the trial; the ability to obtain and maintain regulatory approval of IV 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 Company's ability to pay its debt; 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 meloxicam and Dex-IN and other factors discussed in the Risk Factors set forth in the Company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission (SEC) and in other filings the Company makes with the SEC from time to time. In addition, the forward-looking statements included in this press release represent the Company's views only as of the date of this press release. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements, and as such we anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

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