

# Recro Pharma Completes Enrollment in Phase III Safety Study of IV Meloxicam

## Company on Track to File NDA with U.S. FDA in Summer 2017

MALVERN, Pa., Feb. 27, 2017 (GLOBE NEWSWIRE) -- Recro Pharma, Inc. (Nasdaq:REPH), a revenue generating specialty pharmaceutical company focused on products for hospital and other acute care settings, currently developing non-opioid products for the treatment of serious acute pain, today announced completion of enrollment for its double-blind Phase III safety study evaluating the safety and tolerability of intravenous (IV) meloxicam (N1539) following major surgery.

In this multicenter, randomized, double-blind, placebo-controlled clinical trial, over 700 patients were enrolled and randomly assigned to receive a postoperative regimen of IV meloxicam (30mg bolus injection) or placebo in a 3:1 ratio, once every 24 hours for up to 7 doses following a variety of major elective surgical procedures, including total hip and knee replacements, hernia repair, and spinal, colorectal, and other major surgeries.

“This is an important milestone in the clinical development of IV meloxicam, and marks the completion of enrollment in the third Phase III trial in Recro’s lead development program,” said Gerri Henwood, Recro Pharma’s President and Chief Executive Officer. “We continue to plan to file a New Drug Application (NDA) filing in the summer of 2017.”

### About IV/IM Meloxicam

Meloxicam is a long-acting, preferential COX-2 inhibitor that possesses analgesic, anti-inflammatory and antipyretic activities, which are believed to be related to the inhibition of cyclooxygenase (COX) and subsequent reduction in prostaglandin biosynthesis. IV meloxicam was designed using NanoCrystal® platform, a technology that enables enhanced bioavailability of poorly water-soluble drug compounds.

### About Recro Pharma, Inc.

Recro Pharma is a revenue generating specialty pharmaceutical company focused on products for hospital and other acute care settings that is 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 post-operative pain, which has completed four successful Phase II clinical trials in post-operative pain conditions and two pivotal Phase III efficacy trials and today has reported completion of enrollment in its remaining Phase III study. 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 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 injectable meloxicam; unfavorable new clinical data and additional analyses of existing clinical data; the ability to obtain and maintain regulatory approval of injectable meloxicam, 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 and payment of milestones; 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 injectable meloxicam 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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