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# Recro Pharma Reports Positive Top-Line Results from Pivotal Phase III Clinical Trial of IV Meloxicam

*IV Meloxicam Achieves Primary Endpoint in First of Two Pivotal Trials*

*Fifteen of Nineteen Secondary Endpoints Also Met*

*Management to Host Conference Call and Webcast Today at 5:00 PM ET*

MALVERN, PA, July 26, 2016 – Recro Pharma, Inc. (Nasdaq:REPH), a revenue generating specialty pharmaceutical company focused on products for hospital and ambulatory care settings that is currently developing non-opioid products for the treatment of serious acute pain, today announced positive results from its Phase III clinical trial evaluating intravenous (IV) meloxicam (N1539) for the treatment of acute postoperative pain in patients following bunionectomy surgery. In the trial, IV meloxicam achieved the primary endpoint of a statistically significant difference in Summed Pain Intensity Difference (SPID) over the first 48 hours (SPID48) compared to placebo.

In this multicenter, randomized, double-blind, placebo-controlled clinical trial, 201 patients were enrolled and randomly assigned to receive a postoperative regimen of IV meloxicam (30mg bolus injection over 15-30 seconds) or placebo in a 1:1 ratio, once every 24 hours for up to 3 doses following bunionectomy surgery, a representative hard tissue surgery. The IV meloxicam treatment arm demonstrated a statistically significant reduction in SPID48 ( $p=0.0034$ ) compared to the placebo arm. The study also achieved 15 of the 19 secondary endpoints, including statistically significant differences in SPID6 ( $p=0.0153$ ), SPID12 ( $p=0.0053$ ), SPID24 ( $p=0.0084$ ), SPID24-48 ( $p=0.0050$ ), time to first use of rescue medication ( $p=0.0076$ ), and several other rescue use and pain relief metrics during the first 48 hours, compared to placebo.

The safety results demonstrated that IV meloxicam was well tolerated with no serious adverse events or bleeding events in the IV meloxicam-treated patients. The most common ( $\geq 3\%$ ) adverse events (AEs) were nausea, headache, pruritus, constipation vomiting, dizziness, flushing and somnolence, and were comparable to the placebo group. The IV meloxicam-treated patients experienced injection site pain and injection site erythema at a rate comparable to placebo. The majority of treatment emergent AEs (TEAEs) were mild in nature and there were no discontinuations due to AEs. There were no meaningful differences between treatment groups in vital signs, ECGs or clinical lab assessments.

“The data from this trial demonstrated that IV meloxicam provided rapid and sustained pain relief following bunionectomy surgery, a favorable safety and tolerability profile, and a

statistically significant increase in time to opioid rescue medication,” said Neil Singla, M.D., Chief Scientific Officer of Lotus Clinical Research, and lead investigator of the study. “There are limited non-opioid pain relief options for postoperative patients suffering from moderate-to-severe pain, and these data support that, if approved, IV meloxicam has the potential to provide an important new non-opioid analgesic option for physicians and patients.”

“The exciting data from this pivotal clinical trial continues to build upon the previously demonstrated success of the Phase II program for IV meloxicam in the acute postoperative setting,” said Gerri Henwood, Recro Pharma’s President and Chief Executive Officer. “Importantly, clinicians have expressed an urgent need for non-opioid pain relief alternatives, yet there are limited options for patients recovering from surgery. These data underscore IV meloxicam’s clinical utility and its potential to play a meaningful role as the only IV, 24-hour duration product in the physician’s analgesic toolkit for moderate-to-severe pain.”

Ms. Henwood continued: “We continue to enroll patients in our second ongoing Phase III trial evaluating IV meloxicam following “mini” abdominoplasty surgery and we remain on track to report top-line results from that trial by the end of the fourth quarter of 2016. Assuming positive results from the second pivotal Phase III trial, we believe we will file a New Drug Application for IV meloxicam mid-summer 2017.”

The parameters of: “Time to perceptible pain relief,” “Time to meaningful pain relief,” “Proportion of patients with >50% improvement at 6 hours”, and “Patient’s global assessment (PGA) of pain control at 24 hours”, were not significantly different between treatment groups.

Recro plans to submit additional data from this Phase III clinical trial for presentation at a future scientific conference or in a journal publication.

### **Conference Call and Webcast**

Recro Pharma management will be hosting a conference call and webcast today beginning at 5:00 p.m. ET. To access the conference call, dial 844-243-4691 (U.S. and Canada) or 225-283-0379 (international callers) and enter the conference ID number: 55494048. A webcast will be available in the investor relations section of the company’s website, [www.recropharma.com](http://www.recropharma.com). A replay of the call and webcast will begin approximately two hours after the live call has ended. To access the replay, dial 855-859-2056 (U.S. and Canada) or 404-537-3406 (international callers) and enter the conference ID number: 55494048.

### **About Bunionectomy Surgery**

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 postoperative pain. In the past, drugs that have demonstrated analgesic effectiveness following bunionectomy surgery have frequently translated that analgesic success into other postoperative procedures that result in moderate-to-severe, acute pain.

## **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®. IV/IM meloxicam was designed using NanoCrystal® platform, a technology that enables enhanced bioavailability of poorly water-soluble drug compounds. Recro acquired IV/IM meloxicam from Alkermes in April 2015.

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

Recro Pharma is a revenue generating specialty pharmaceutical company focused on products for hospital and ambulatory 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 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 injectable 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 injectable 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 injectable 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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