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# Recro Pharma Announces Successful Top-Line Results from Phase III Safety Study of IV Meloxicam

*IV Meloxicam 30mg Continues to Demonstrate Solid Safety and Tolerability Profile*

*Company on Track to File NDA with U.S. FDA in Early Q 3 2017*

*Recro Completes Largest Phase 3 Double Blind Placebo Controlled Non-Opioid Trial Evaluating Safety of IV Pain Product in Post-Operative Setting*

MALVERN, Pa., May 09, 2017 (GLOBE NEWSWIRE) -- Recro Pharma, Inc. (Nasdaq:REPH), a revenue generating specialty pharmaceutical company focused on therapeutics for hospital and other acute care settings, today announced successful top-line results from its Phase III safety study evaluating intravenous (IV) meloxicam (30mg bolus injection) following major surgery. The primary objective of the study was to evaluate the safety and tolerability of IV meloxicam 30mg vs. placebo through Day 28 following treatment. The study demonstrated that the adverse event profile of IV meloxicam 30mg was consistent with previously completed studies, and was similar to placebo. Recro Pharma believes the results of this 722 patient Phase III safety study support the safety profile of IV meloxicam 30mg and completes the last clinical requirement of the full efficacy and safety program for a New Drug Application (NDA) for IV meloxicam 30mg as a novel, non-opioid for management of moderate to severe pain.

This multicenter, randomized, double-blind, placebo-controlled Phase III clinical trial, included patients who had undergone major elective surgical procedures which were expected to result in hospitalization for at least 24-48 hours. Major surgical procedures included total hip and knee replacements, spinal, GI, hernia repair, and gynecologic surgeries, as well as a range of other surgeries. Patient demographics were balanced across treatment groups and included 40% male patients and about 23% of patients who were over age 65. Unlike the pivotal efficacy trials, minimum pain scores were not required for treatment. Sites were permitted to use opioids and other pain management modes according to their “standard of care” and meloxicam or placebo was added to this regimen. Patients were randomized in a 3:1 ratio to receive either IV meloxicam 30mg or IV placebo daily for up to 7 doses. A total of 721 patients received at least one dose of study medication.

The most common (≥3%) adverse events (AEs) observed in the IV meloxicam 30mg treatment group (n=538) are listed in the table below:

| | n (%) of Subjects | |
|---|---|---|
| | 30mg | Placebo |
| **Preferred Term** | **N = 538** | **N = 183** |
| Subjects with ≥1 AE | 339 (63.0) | 119 (65.0) |
| Nausea | 123 (22.9) | 51 (27.9) |
| Constipation | 51 (9.5) | 17 (9.3) |
| Vomiting | 27 (5.0) | 14 (7.7) |
| Pruritis | 21 (3.9) | 10 (5.5) |
| Gamma-glutamyl transferase (GGT) increased | 21 (3.9) | 5 (2.7) |
| Headache | 20 (3.7) | 12 (6.6) |
| Anemia | 18 (3.3) | 4 (2.2) |

In patients age 65 and over, the percentage of patients reporting at least one AE was approximately 7% less in the IV meloxicam 30mg treatment arm compared to the placebo arm. The total occurrence of patients with at least one serious adverse event (SAE) was observed to be lower in the IV meloxicam 30mg group, 2.6%, (14/538 meloxicam patients) than in the placebo group, 5.5%, (10/183 placebo patients). In this safety study only two SAE events were listed as possibly related to study treatment. Both of these SAEs occurred in one placebo treated patient. No deaths were reported in either treatment group. Approximately 3% of patients in each study group discontinued.

There were no meaningful differences between treatment groups in vital signs, ECGs, clinical lab assessments and surgeon satisfaction with wound healing. Overall there was low incidence of clinically significant wound healing abnormalities, as scored by the primary investigator, in both treatment groups (~2%). The meloxicam group had 4 patients with more than one attribute scored “clinically significant”, while other patients were scored “clinically significant” for only one attribute.

In addition, overall opioid use was lower, and “time to first use” of opioids was significantly longer, in the IV meloxicam 30mg treatment arm, compared to placebo.

“The positive data reported today from this Phase III safety trial demonstrate that the safety profile for IV meloxicam 30mg is in line with prior studies and similar to placebo in acute postoperative pain in patients following a wide range of major soft and hard tissue surgeries,” said Stewart McCallum, M.D., F.A.C.S., Chief Medical Officer for Recro Pharma. “These data are also important because they continue to support the thesis that, if approved, IV meloxicam 30mg has the potential to be a novel, non-opioid alternative for management of patients with moderate to severe pain, such as pain following major surgery.”

Gerri Henwood, President and Chief Executive Officer of Recro Pharma, commented, “We believe that these safety study results, together with the positive results from our two Phase III efficacy studies, as well as our positive Phase II trials and other safety studies complete the full development program for our planned NDA submission for IV meloxicam 30mg as a novel non-opioid product for management of moderate to severe pain. We believe we remain on track to file the NDA with the U.S. Food and Drug Administration during early Q3 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 a NanoCrystal® platform, a technology that enables enhanced bioavailability of poorly water-soluble drug compounds.

**About Recro Pharma, Inc.**

Recro is a specialty pharmaceutical company that operates through two business divisions, an Acute Care, hospital product division and a revenue-generating contract development and manufacturing, or CDMO division, located at the Company's Gainesville facility. The Acute Care division is primarily focused on developing innovative products for hospital and other acute care settings. The Company's lead product candidate is a proprietary injectable form of meloxicam, a long-acting preferential COX-2 inhibitor. IV meloxicam has successfully completed four Phase II clinical trials in the management of moderate to severe post-operative pain and two pivotal Phase III clinical efficacy trials in patients following bunionectomy and abdominoplasty surgeries, as well as a large double blind Phase III safety trial and other safety studies. As injectable meloxicam is in the non-opioid class of drugs, the Company believes it will overcome many of the issues associated with commonly prescribed opioid therapeutics, including respiratory depression, constipation, excessive nausea and vomiting, as well having no addictive potential while maintaining meaningful analgesic effects for relief of pain. The Company's CDMO division leverages its formulation expertise to develop and manufacture pharmaceutical products using its proprietary delivery technologies and other manufacturing services for commercial partners who commercialize or plan to commercialize these products. These collaborations can result in revenue streams including royalties, profit sharing, research and development and manufacturing fees, which support continued operations for its CDMO division and it contributes non-dilutive funding for the development and pre-commercialization activities of its Acute Care division.

**Cautionary Statement Regarding Forward-Looking Statements**

This press release contains forward-looking statements that involve risks and uncertainties. Such forward looking statements reflect Recro'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 or its management, are intended to identify such forward-looking statements. These forward looking statements are based on information available to Recro as of the date of this press release and are subject to a number of risks, uncertainties, and other factors that could cause Recro's performance to differ materially from those expressed in, or implied by, these forward looking statements. Recro assumes no obligation to update any such forward-looking statements. Factors that could cause Recro'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 injectable meloxicam, the preparation and filing of other portions of the drug application, including CMC, the ability to obtain and maintain regulatory approval of injectable meloxicam and, and the labeling under any such approval, regulatory developments in the United States and foreign countries; the Company's ability to achieve its financial goals, including financial guidance: the Company's ability to raise future financing for continued development and the payment of milestones; the Company's ability to pay its debt; customer product performance and ordering patterns, 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; and the

successful commercialization of injectable meloxicam. In addition, the forward looking statements in this press release should be considered together with the risks and uncertainties that may affect Recro's business and future results included in Recro's filings with the Securities and Exchange Commission at www.sec.gov. Recro assumes no obligation to update any such forward looking statements.

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