September 5, 2017

Recro Pharma Presents Phase III IV Meloxicam Clinical Safety and Opioid Use Data at PAINWeek® 2017

IV Meloxicam 30mg Demonstrates Statistically Significant Reductions in Opioid Consumption in Overall Study Population and Important Subpopulations, Including in Patients Following Major Orthopedic Surgery and Advanced Age, Renally Impaired Patients

Continues to Demonstrate Favorable Safety and Tolerability Profile

MALVERN, Pa., Sept. 05, 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 three poster presentations at PAINWeek 2017, taking place September 5-9, 2017, in Las Vegas, NV. The poster presentations report safety and opioid use data from the Company's recently completed Phase III safety study evaluating intravenous (IV) meloxicam 30mg following major surgery, and reflect important acute, postoperative pain subpopulations, including patients who underwent major orthopedic surgeries and advanced age patients with impaired renal function.

"The clinical data being presented at PAINWeek this year continue to demonstrate that IV meloxicam 30mg has a favorable safety and tolerability profile, including in a subpopulation of patients over age 65 with renal impairment who are at an increased risk of complications and toxicities associated with NSAID use," said Stewart McCallum, M.D., F.A.C.S., Chief Medical Officer of Recro Pharma. "Importantly, IV meloxicam 30mg also demonstrated statistically significant reductions in opioid consumption resulting in a 22-34% reduction in the overall study population, a 31-57% reduction in the subpopulation of patients over age 65 with renal impairment, and a 26-38% reduction in patients undergoing major orthopedic surgeries, a very common group of procedures where patients experience moderate to severe postoperative pain lasting multiple days following surgery. Collectively, we believe these Phase III results demonstrate the differentiated safety profile and significant potential of IV meloxicam 30mg as a new non-opioid treatment option for acute, postoperative pain."

IV meloxicam 30mg has successfully completed three Phase III trials, including two Phase III efficacy trials and one Phase III safety trial. The results from these studies, as well as results from four Phase II trials and other safety studies, comprised the NDA package for IV meloxicam 30mg submitted to the U.S. Food and Drug Administration in July 2017.

Details for the poster presentations at PAINWeek:

All posters will be on display in Condesa Commons on Level 2 of the Cosmopolitan of Las Vegas from 3:30 pm PT on Wednesday, September 6 through 4:30 pm PT on Friday,

September 8.

Title: Safety and Opioid Use Following Major Orthopedic Surgery in a Phase 3, Placebo-Controlled Study of Intravenous Meloxicam
Poster #: 77
Summary: This poster reports study findings within the population of patients (n=379) who underwent major orthopedic surgeries, including joint replacements, complex foot, bunionectomy, spinal, and other procedures. These patients were randomized (3:1) and administered IV meloxicam 30mg (n=283) or placebo (n=96) via IV push over 15-30 seconds every 24 hours for up to 7 doses. Subjects could continue to receive opioid analgesia according to the practice of the investigator to treat uncontrolled pain symptoms; additional NSAIDs were prohibited during inpatient treatment. The majority of subjects (>85%) received 2 or 3 doses of study drug. In this orthopedic patient population, IV meloxicam 30mg was well tolerated with no deaths, and a low incidence of SAEs (2.5% of IV meloxicam vs. 4.2% of placebo) and withdrawals due to an AE (0.4% of IV meloxicam vs. 0% of placebo). AEs were generally mild or moderate in intensity, and similar between treatments. The most common treatment-emergent AEs included nausea, constipation, vomiting, increased gamma-glutamyltransferase, headache, anaemia, insomnia, hypotension and pruritis. Importantly, mean opioid consumption was lower for IV meloxicam 30mg compared with placebo at all evaluated intervals, reaching statistical significance ($p<0.05$) in the Hour 0-24, Hour 24-48, Hour 48-72, and Hour 0-72 intervals with 27.4%, 26.1%, 38.4%, and 25.8% reductions in opioid use, respectively. A lower incidence of nausea and vomiting was observed in the IV meloxicam 30mg arm, which may have been related to the reduction in opioid use compared with placebo.

Title: Safety and Opioid Use in a Phase 3, Placebo-Controlled Study of Intravenous Meloxicam Following Major Surgery
Poster #: 78
Summary: This poster reports study findings from the overall Phase 3 safety study population (n=721). Following various major elective surgeries, including orthopedic, abdominal, gynecologic, spinal, and other procedures, patients were randomized (3:1) and administered IV meloxicam 30mg (n=538) or placebo (n=183) via IV push over 15-30 seconds every 24 hours for up to 7 doses. Subjects could continue to receive opioid analgesia according to the practice of the investigator to treat uncontrolled pain symptoms; additional NSAIDs were prohibited during inpatient treatment. The majority of subjects (>80%) received 2 or 3 doses of study drug during their inpatient stay. In the overall study population, IV meloxicam 30mg was well tolerated with no deaths, and a low incidence of SAEs (2.6% of IV meloxicam vs. 5.5% of placebo) and withdrawals due to an AE (0.4% of IV meloxicam vs. 0% of placebo). AEs were generally mild or moderate in intensity, and similar in incidence between treatments. The most common treatment-emergent AEs included nausea, constipation, vomiting, headache, pruritus, increased gamma-glutamyltransferase, dizziness, and anemia. Importantly, mean opioid consumption was numerically lower in the IV meloxicam 30mg group compared with placebo at all evaluated intervals, reaching statistical significance ($p<0.05$) in the Hour 0-24, Hour 24-48, Hour 48-72 and Hour 0-72 intervals with 22.0%, 23.9%, 33.9 and 23.2% reductions in opioid use, respectively. There was a lower rate of nausea and vomiting observed in the IV meloxicam 30mg arm, which may have been related to the reduction in opioid use compared with placebo.

Title: Safety and Opioid Use in Subjects of Advanced Age with Impaired Renal Function in a

Phase 3, Placebo-Controlled Study of Intravenous Meloxicam Following Major Surgery
Poster #: 79
Summary: This poster reports study findings within the population of patients (n=119) of advanced age (66 to 80 years, with a mean age of 70.5 years) with impaired renal function (Glomerular Filtration Rate ≤89 mL/min/1.73 m2). These patients were randomized (3:1) and administered IV meloxicam 30mg (n=88) or placebo (n=31) via IV push over 15-30 seconds every 24 hours for up to 7 doses. Subjects could continue to receive opioid analgesia according to the practice of the investigator to treat uncontrolled pain symptoms; additional NSAIDs were prohibited during inpatient treatment. The majority of subjects (>80%) received 2 or 3 doses of study drug during their inpatient stay. In this high risk patient population, IV meloxicam 30mg was well tolerated, with no deaths or discontinuations due to adverse events (AEs), and a low incidence of SAEs (2.3% of IV meloxicam vs. 12.9% of placebo). AEs were generally mild or moderate in intensity, and similar between treatments. The most common treatment-emergent AEs included nausea, constipation, vomiting, anaemia, pruritus, increased gamma-glutamyltransferase, insomnia and urinary retention. Importantly, mean opioid consumption was numerically lower in the IV meloxicam 30mg group compared with placebo at all evaluated intervals, reaching statistical significance ($p<0.05$) in the Hour 0-24, Hour 24-48, Hour 48-72, and Hour 0-72 intervals with 30.5%, 41.9%, 56.9%, and 33.8% reductions in opioid use, respectively.

The official PAINWeek poster reception will be held at Condesa Commons on Level 2 on Thursday, September 7, from 6:30 – 8:30 pm PT. A Recro Pharma sponsored poster reception will also be held at the same time near the Recro Pharma posters.

Downloadable copies of the posters can be accessed by visiting the “Investors” section of the Recro Pharma website and by clicking “Presentations.”

For more information on PAINWeek, visit: https://www.painweek.org/

More About the Phase III Safety Study

The multicenter, randomized, double-blind, placebo-controlled Phase III clinical trial (NCT02720692), enrolling patients who had undergone major elective surgical procedures, which were expected to result in hospitalization for at least 24-48 hours, was designed to evaluate the safety and tolerability of IV meloxicam 30mg in patients following major elective surgery. 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. 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.

About IV/IM Meloxicam 30mg

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 30mg was designed using the NanoCrystal® platform, a technology that enables

enhanced bioavailability of poorly water-soluble drug compounds. NanoCrystal® is a registered trademark of Alkermes Pharma Ireland Limited (APIL).

About Recro Pharma, Inc.

Recro Pharma 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 30mg has successfully completed two pivotal Phase III clinical efficacy trials in patients following bunionectomy and abdominoplasty surgeries, a large double blind Phase III safety trial, four Phase II clinical trials for the management of moderate to severe post-operative pain, as well as 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 as 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: 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; results and timing of the clinical trials of injectable meloxicam, 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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