April 11, 2019

Recro Pharma Announces Presentation of New Meta-Analysis for IV Meloxicam at the 44th Annual Regional Anesthesiology and Acute Pain Medicine Meeting

New Meta-Analysis Data Suggests IV Meloxicam Produces Largest SPID, Greater Reduction in Opioid Use and Better Safety Profile Compared to Other Non-Opioid Medications for Moderate to Severe Pain

Abstract Among the Highest Scoring Presentations at the Meeting

MALVERN, Pa., April 11, 2019 (GLOBE NEWSWIRE) -- Recro Pharma, Inc. (Nasdaq:REPH), a specialty pharmaceutical company with a high-performing revenue generating contract development and manufacturing (CDMO) segment, today announced a moderated poster presentation highlighting new intravenous (IV) meloxicam data at the 44th Annual Regional Anesthesiology and Acute Pain Medicine Meeting, hosted by the American Society of Regional Anesthesia and Pain Medicine, taking place April 11-13, 2019, in Las Vegas.

The abstract was a highly scored submission, and was selected for a five minute oral presentation. In this study, the researchers conducted a network meta-analysis (NMA) assessing the safety and efficacy of IV meloxicam relative to other IV non-opioid analgesics for moderate to severe pain. The analysis was conducted by comparing Recro Pharma's IV meloxicam data to 17 randomized controlled clinical trials evaluating several non-opioid analgesics, including acetaminophen, ketorolac, placebo combined with a non-opioid and placebo combined with an opioid, across three procedure categories: abdominal, bunionectomy and orthopedic.

A pooled analysis of pain outcomes across all bunionectomy procedure studies and time points demonstrated a probability of 84% that IV meloxicam produced the largest sum of pain intensity difference (SPID). A pooled analysis of pain outcomes across all abdominal procedure studies and time points demonstrated a probability of 72% that IV meloxicam produced the largest SPID. Both of these outcomes are consistent with the Surface Under Cummulative Ranking Curve (SUCRA) rankings. IV meloxicam could not be evaluated against other non-opioid IV analgesics in orthopedic procedures due to a lack of reported pain score data for IV meloxicam in orthopedic procedures. IV meloxicam was associated with a pooled 18% reduction in morphine (milligram equivalent) utilization (range 25% to 12%), compared to a 16% reduction for ketorolac and a 14% reduction for acetaminophen.

For safety, IV meloxicam was associated with lower pooled odds of gastrointestinal opioid-related adverse events (ORADEs) (OR=0.72; 95% credible interval [Crl] 0.66-0.78) and respiratory ORADEs (OR=0.51; 95% Crl 0.42-0.59). IV meloxicam offered no relative benefits with respect to adverse events (AEs) not related to opioids.

"These data show that IV meloxicam is associated with lower pain, morphine utilization and opioid-related AEs postoperatively across a number of important clinical comparisons," said Stewart McCallum, M.D., F.A.C.S., Chief Medical Officer of Recro Pharma. "We continue to believe that IV meloxicam would be an attractive non-opioid pain management candidate for the hospital marketplace, and we are committed to working closely with the U.S. Food and Drug Administration to bring it to the physicians and patients who could benefit from it."

Details for the moderated presentation are as follows:

Title: Network Meta-Analysis to Evaluate Intravenous Meloxicam versus other Intravenous Non-Opioid Medications for Moderate-Severe Postoperative Pain
Lead author: John Carter, MS
ID number: 7309; MP-07a
Date and time: Friday, April 12, 2019 from 1:45-3:15pm
Location: Cesar's Palace – Room: Patrician

A downloadable copy of the poster can be accessed following conclusion of the presentation by visiting the "Investors" section of the Recro Pharma website and clicking "Presentations."

For more information on this meeting, visit:https://www.asra.com/.

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 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 in Gainesville, GA. The Acute Care division is primarily focused on developing innovative products for the 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 two pivotal Phase III clinical efficacy trials, a large double-blind placebo-controlled Phase III safety trial and four Phase II clinical efficacy trials, as well as other safety studies. On March 22, 2019 Recro announced that FDA had provided a second CRL in response to the Company's NDA for IV meloxicam. The Company is evaluating the path forward for IV meloxicam and plans to schedule a meeting with the FDA. As injectable meloxicam is in the non-opioid class of drugs, if approved, the Company believes it has the potential to 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 and development-stage 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," "may," "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 Company's ability to attract a strategic partner for the development and commercialization of IV meloxicam, the Company's ability to adequately resolve the deficiencies identified by the FDA in the second CRL for IV meloxicam, and the time frame associated with any such resolution, including whether the FDA will require additional clinical studies and the time and cost of such studies; whether the Company will prepare an amended new drug application (NDA) for IV meloxicam and, whether the FDA will accept and approve any such resubmitted NDA and the labeling under any such approval; the Company's ability to raise future financing for continued product development and IV meloxicam commercialization; with regard to the Company's clinical trial results, whether there may be changes in the interpretation by the FDA of the data of the Company's clinical trials and the length, cost and uncertain results and timing of our ongoing clinical trials; with regard to the potential commercial opportunity of IV meloxicam, whether any FDA approval of IV meloxicam will include labeling restrictions and the potential that IV meloxicam does not receive regulatory approval or does not receive reimbursement by third party payors, that IV meloxicam is not accepted by the medical community, including physicians, patients, health care providers and hospital formularies or that a commercial market for IV meloxicam does not develop; the Company's ability to manage costs and execute on its operational and budget plans, the Company's ability to achieve its financial goals, including financial guidance, the Company's ability to pay its debt under its credit agreement; the Company's ability to maintain relationships with CDMO commercial partners; and the Company's ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection. 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.

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