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Recro Pharma Announces Publication of Phase III IV Meloxicam Clinical Safety and Opioid Use Data in the Journal Clinical Pharmacology in Drug Development

Publication Highlights That IV Meloxicam Has a Safety Profile Similar to Placebo and Reduces Opioid Consumption

MALVERN, Pa., February 25, 2019 (GLOBE NEWSWIRE) -- Recro Pharma, Inc. (NASDAQ:REPH), a revenue generating specialty pharmaceutical company focused on therapeutics for hospitals and other acute care settings, today announced the publication of clinical data from its Phase III study evaluating the safety of intravenous (IV) meloxicam in patients following major elective surgery. The article, titled "A Phase 3, Randomized, Placebo-controlled Evaluation of the Safety of Intravenous Meloxicam Following Major Surgery," was published online in the medical journal *Clinical Pharmacology in Drug Development*. A New Drug Application (NDA) for IV meloxicam is currently under review by the U.S. Food and Drug Administration (FDA) and the Company is currently awaiting its assigned PDUFA goal date of March 24, 2019.

"Acute pain following surgery can have significant impacts on clinical outcomes and evidence suggests that a large proportion of postsurgical patients still report moderate to severe levels of pain," said Sergio D. Bergese, MD, Ohio State University, Wexner Medical Center, and lead author of the publication. "Opioids have been a mainstay of postoperative pain management, but they are clearly associated with several adverse events and other important risks. These published data suggest that IV meloxicam has a safety profile similar to placebo with respect to numbers and frequencies of adverse events (AEs), while meaningfully reducing opioid consumption for patients with moderate to severe postoperative pain."

"The results from this study demonstrate that IV meloxicam 30mg was generally well tolerated and had an opioid-reducing effect when administered to subjects with moderate to severe pain following a variety of elective surgical procedures," said Stewart McCallum, M.D., Chief Medical Officer of Recro Pharma. "We believe IV meloxicam can be a valuable component of multi-modal pain management in the postsurgical setting and we continue to educate physicians and other healthcare professionals about the potential benefits of IV meloxicam as we await the upcoming PDUFA goal date of March 24, 2019."

The published article describes data from a randomized, multicenter, double-blind, placebo-controlled Phase III clinical trial where IV meloxicam (30mg) or placebo (3:1 randomization) was administered to patients (n=721) who had undergone major elective surgical

procedures, including total hip or knee replacements, spinal, gastrointestinal, hernia repair or gynecologic surgeries, among a range of other surgeries. Safety was evaluated via adverse events (AEs), clinical laboratory tests, vital signs, wound healing, and opioid consumption. The incidence of AEs was similar between IV meloxicam and placebo groups (63.0% versus 65.0%). Investigators assessed most AEs as mild or moderate in intensity. AEs of interest (e.g., injection-site reactions, bleeding, cardiovascular, hepatic, renal, thrombotic, and wound-healing events) were similar between groups. A greater frequency of serious adverse events (SAEs) occurred in the placebo group (5.5%) versus the IV meloxicam group (2.6%). The most common SAEs were infections (IV meloxicam, n=3 [0.6%]; placebo, n=2 [1.1%]), procedural complications (IV meloxicam, n=6 [1.1%]; placebo, n=3 [1.6%]), and gastrointestinal events (IV meloxicam, n=4 [0.7%]; placebo, n=2 [1.1%]). There were no deaths during the study.

Mean opioid consumption, measured by converting opioid analgesic doses to the IV morphine equivalent dose, was numerically lower in the IV meloxicam group compared with the placebo group at all time points (hours 0-24, 24-48, 48-72, 0-48, and 0-72 hours) and reached statistical significance at hours 0-24, 0-48, and 0-72. Over the treatment period, IV meloxicam was associated with a 23.6% reduction in total opioid use compared to the placebo group. The total IV morphine equivalent dose was 9.2mg lower among IV meloxicam-treated patients, compared to placebo-treated patients, although the difference was not statistically significant (29.8mg versus 39.0mg; p=0.0531).

The full publication can be accessed here.

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. Recro's Complete Response to the CRL for IV meloxicam was accepted for filing by the FDA in early October 2018 and assigned a PDUFA date of March 24, 2019. 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 resolve the deficiencies identified by the FDA in the CRL for IV meloxicam; whether the FDA will approve the Company's amended NDA for IV meloxicam and, if approved, the labeling under any such approval; if the FDA does not approve the Company's amended NDA, the time frame otherwise associated with resolving the deficiencies identified by the FDA in the CRL and whether the FDA will require additional clinical studies to support the approval of IV meloxicam and the time and cost of such studies; the Company's ability to successfully launch and commercialize IV meloxicam, if approved; the length, cost and uncertain results and timing of the Company's clinical trials, including the Company's Phase IIIb clinical trials and any additional clinical trials that the FDA may require in connection with IV meloxicam; the extent to which IV meloxicam, if approved, is accepted by the medical community, including physicians, patients, health care providers and hospital formularies; the availability of coverage and adequate and timely reimbursement for IV meloxicam, if approved; the Company's ability to raise future financing for continued product development, IV meloxicam commercialization and the payment of milestones; the Company's ability to achieve its financial goals, including financial guidance; the Company's ability to access funding and pay its debt under its credit agreement; regulatory developments in the United States and foreign countries; customer product performance and ordering patterns, the performance of third-party suppliers and manufacturers; 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. In particular, there can be no assurance that the FDA will complete its review by the PDUFA goal date, that the FDA will not require changes or additional data with respect to the amended NDA or that the FDA will approve the amended NDA. 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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