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Recro Pharma Announces Publication of Phase II IV Meloxicam Abdominal Hysterectomy Data in *Anesthesia & Analgesia*

MALVERN, Pa., Nov. 14, 2018 (GLOBE NEWSWIRE) -- Recro Pharma, Inc. (NASDAQ:REPH), a revenue generating specialty pharmaceutical company focused on therapeutics for the hospital and other acute care settings, today announced the publication of previously reported Phase II clinical data for intravenous (IV) meloxicam for the treatment of pain following open abdominal hysterectomy. The article, titled "Analgesic Efficacy and Safety of Intravenous Meloxicam in Subjects with Moderate-to-Severe Pain After Open Abdominal Hysterectomy: A Phase 2 Randomized Clinical Trial," was published online in *Anesthesia & Analgesia*.

"These results from our Phase II trial evaluating IV meloxicam for the management of moderate to severe pain following abdominal hysterectomy surgery highlight IV meloxicam's analgesic effect, coupled with a favorable safety and tolerability profile, in a soft tissue surgical model," said Stewart McCallum, M.D., Chief Medical Officer of Recro Pharma. "Additionally, these data provide supportive evidence suggesting IV meloxicam's ability to reduce the need for rescue opioid consumption, a critical need in today's postoperative pain treatment landscape."

The Phase II, multi-center, randomized, double-blind, placebo- and active (morphine)-controlled trial (n=486) was designed to evaluate the efficacy and safety of five dose groups (5mg, 7.5mg, 15mg, 30mg and 60mg) of IV meloxicam for the management of moderate to severe pain following open abdominal hysterectomy. The co-primary efficacy endpoints were the summed pain intensity difference (SPID) over the first 24 hours post-dose (SPID₂₄) and the sum of the time-weighted pain relief scores over the first 24 hours post-dose (TOTPAR₂₄). IV meloxicam provided significant analgesic effect and, in general, was well tolerated. All evaluated IV meloxicam doses produced statistically significant improvements in SPID₂₄ and TOTPAR₂₄ relative to placebo, and IV meloxicam doses 15mg and greater had significantly improved SPID₂₄ and TOTPAR₂₄ relative to morphine. Additionally, IV meloxicam was associated with a significantly reduced need for rescue medication; total rescue opioid consumption was 42-71% lower for all evaluated IV meloxicam doses compared to the placebo group, and three IV meloxicam doses (15mg, 30mg and 60mg) were associated with significantly lower overall rescue opioid consumption compared to the morphine group.

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 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, 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," "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 pay its debt; regulatory developments in the United States and foreign countries; customer product performance and ordering patterns, the performance of third-party suppliers and manufacturers; 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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