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Recro Pharma Announces Presentation of New Data Demonstrating IV Meloxicam's Effect on Platelet Function at the 72nd PostGraduate Assembly in Anesthesiology

MALVERN, Pa., Dec. 10, 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 a poster presentation highlighting intravenous (IV) meloxicam's effect on platelet function at the 72nd PostGraduate Assembly in Anesthesiology (PGA72), sponsored by the New York State Society of Anesthesiologists (NYSSA), taking place December 7-11, 2018, in New York City.

The poster, titled "An Ex-vivo Assessment of the Effects of Meloxicam IV on Platelet Function," which was presented by lead author Jonathan S. Jahr, M.D., David Geffen School of Medicine at UCLA, describes results from an *ex vivo* study assessing the effects of various concentrations of IV meloxicam (5mcg/mL, 10mcg/mL, 15mcg/mL and 20mcg/mL) on platelet function compared to ketorolac (2.5mcg/mL and 5mcg/mL) and an untreated control. The 5mcg/mL concentration of IV meloxicam in this study corresponds to the maximum plasma levels following a 30mg dose in the clinical setting. Similarly, the 5mcg/mL concentration of ketorolac in this study corresponds to a 30mg and the 2.5mcg/mL dose corresponds to the 15mg dose in the clinical setting. In this study, blood samples provided by healthy volunteers (n=8) were analyzed to determine closure time (CT) following the addition of IV meloxicam and ketorolac at the previously mentioned concentrations to the blood plasma samples. The researchers conducted the analyses using a platelet function analyzer (PFA-100), a standard of care for platelet function testing, and two different reagents, collagen with epinephrine (CEPI) and collagen with adenosine diphosphate (CADP).

In the CEPI reagent analysis, a significant treatment effect was observed for changes in CT ($p=0.0441$). No significant difference was observed in CT for the IV meloxicam treated samples versus the untreated control at any of the evaluated concentrations ($p\geq 0.5400$). When compared to untreated control, the ketorolac treated sample CT values were significantly prolonged in both the 2.5mcg/mL and the 5mcg/mL concentrations ($p\leq 0.0257$). All IV meloxicam concentration levels had a significantly shorter CT compared to the 2.5mcg/mL ketorolac concentration ($p<0.005$). All IV meloxicam concentration levels had numerically shorter CTs compared to the 5mcg/mL ketorolac concentration, though only the 10mcg/mL IV meloxicam concentration reached statistical

significance. In the CADP reagent analysis, neither IV meloxicam nor ketorolac demonstrated a significant change in CT versus untreated control ($p \geq 0.0907$).

“A concern around the use of non-steroidal anti-inflammatory drugs (NSAIDs) in the peri- or post-operative setting is the potential for platelet dysfunction and risk of bleeding related events,” commented Dr. Jahr. “Our thesis here was that IV meloxicam’s higher affinity for COX-2 inhibition, versus COX-1, would translate into a lower risk for platelet dysfunction. The data presented this year at PGA72 show that IV meloxicam achieved roughly the same closure times (CTs) as untreated controls and numerically shorter CTs than ketorolac. In contrast, significant CT prolongations were observed in ketorolac samples compared with untreated control. These results suggest that IV meloxicam has the potential to provide a meaningful clinical benefit over ketorolac with respect to a decreased risk of platelet dysfunction.”

“NSAIDs are an integral part of the analgesic toolkit and are the physician’s first-line defense to prevent or treat pain,” said Stewart McCallum, M.D., F.A.C.S., Chief Medical Officer of Recro Pharma and co-author of the poster. “These compelling data continue to build upon the growing body of data supporting IV meloxicam’s safety and reinforce the positive safety findings elucidated by our comprehensive IV meloxicam development program. The IV meloxicam New Drug Application is currently under review by the U.S. Food and Drug Administration and we are currently awaiting our PDUFA goal date of March 24, 2019.”

A downloadable copy of the poster can be accessed by visiting the “Investors” section of the [Recro Pharma website](#) and clicking “Presentations.”

For more information on PGA72, visit: <http://www.pga.nyc/>.

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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