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Recro Pharma Announces Publication of Supportive Phase II IV Meloxicam Data in the Journal of Clinical Pharmacology

MALVERN, Pa., Jan. 17, 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 dental impaction surgery. The article, titled "A Randomized Double-Blind Controlled Trial of Intravenous Meloxicam in the Treatment of Pain Following Dental Impaction Surgery," was published online in the Journal of Clinical Pharmacology.

"There is a great need for differentiated non-opioid alternatives for the management of moderate to severe pain, and these supportive Phase II results continue to reinforce the favorable efficacy and safety profile seen to date with IV meloxicam," said Gerri Henwood, President and Chief Executive Officer of Recro Pharma. "At Recro, we continue to execute on our strategy of transforming into a commercial enterprise as we await an approval decision from the U.S. Food and Drug Administration for IV meloxicam 30mg, which is expected in May 2018."

The randomized, controlled, Phase II trial was designed to evaluate the efficacy, safety and tolerability of a single administration of IV meloxicam (15mg, 30mg and 60mg) compared with oral ibuprofen 400mg and placebo following dental impaction surgery. The primary efficacy endpoint was Summed Pain Intensity Difference (SPID) over the first 24 hours (SPID24). IV meloxicam demonstrated a statistically significant difference in SPID24 compared with placebo at each dose level, and IV meloxicam 30mg and IV meloxicam 60mg both demonstrated a statistically significant difference in SPID24 compared with oral ibuprofen 400mg. Additionally, IV meloxicam demonstrated a favorable safety and tolerability profile, with no serious adverse events or discontinuations due to adverse events reported.

The full publication can be accessed here.

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 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, product commercialization 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. 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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