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Recro Pharma Announces Publication of Phase III IV Meloxicam Bunionectomy Data in the Clinical Journal of Pain

MALVERN, Pa., March 27, 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 Phase III clinical data for intravenous (IV) meloxicam for the treatment of pain following bunionectomy surgery. The article, titled ”Efficacy and Safety of Intravenous Meloxicam in Subjects with Moderate-to-Severe Pain Following Bunionectomy,” was published online in the Clinical Journal of Pain.

“As previously reported, the data from this Phase III trial demonstrate that IV meloxicam provides rapid and sustained pain relief following bunionectomy surgery, a favorable safety and tolerability profile, and a significant opioid-sparing effect,” said Stewart McCallum, M.D., Chief Medical Officer of Recro Pharma. “An urgent, unmet medical need for non-opioid agents for the management of moderate to severe pain persists for patients and physicians. The New Drug Application for IV meloxicam is currently under review with the U.S. Food and Drug Administration with a target PDUFA date of May 26, 2018. If approved, IV meloxicam will be the first 24-hour duration, non-opioid, IV analgesic for moderate to severe pain.”

The Phase III, multi-center, randomized, double-blind, placebo-controlled trial (n=201) was designed to evaluate the efficacy and safety of IV meloxicam 30mg for the management of moderate to severe pain following bunionectomy surgery. The primary efficacy endpoint was Summed Pain Intensity Difference (SPID) over 48 hours (SPID48). IV meloxicam 30mg achieved a statistically significant difference reduction in SPID48 ($p=0.0034$), as well as statistically significant reductions in SPID values at other times and intervals (SPID6, SPID12, SPID24, SPID24-48), among other key secondary endpoints. Additionally, an opioid-sparing effect was observed for IV meloxicam 30mg, indicated by a longer time to first use of rescue ($p=0.0076$), a lower number of subjects using rescue ($p<0.001$) and the lower mean number of per-subject rescue doses ($p<0.05$). IV meloxicam 30mg was well tolerated, with no associated serious adverse events (SAEs) or withdrawals due to adverse events (AEs). The majority of treatment-emergent adverse events in the IV meloxicam 30mg group were reported as mild or moderate in intensity, with incidence and intensity comparable to placebo.

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. In 2017, Recro submitted the NDA for IV meloxicam to the FDA for review, it was accepted by the FDA and there is a late May 2018 PDUFA date. 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 Company's ability to obtain and maintain regulatory approval of IV meloxicam and the labeling under any such approval; the Company's ability to successfully launch and commercialize IV meloxicam, if approved; results and timing of the phase IIIb clinical trials of IV meloxicam; the extent to which IV meloxicam, if approved, is accepted by the medical community, including physicians, patients, health care providers and hospital fomularies; 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. 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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