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Recro Pharma Provides Regulatory Update for IV Meloxicam

Company Anticipates NDA Resubmission by the End of September 2018

MALVERN, Pa., Sept. 04, 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 provided a regulatory update following receipt of the official meeting minutes from a July 2018 Type A meeting with the U.S. Food and Drug Administration (FDA) relating to a path forward for intravenous (IV) meloxicam, the Company's lead product candidate for the management of moderate to severe pain.

Recro had requested this Type A meeting with the FDA to address a Complete Response Letter (CRL) it received from the FDA regarding the New Drug Application (NDA) for IV meloxicam. During the meeting, Recro discussed data from ad hoc analyses and selective secondary endpoints of Recro's clinical trials which the FDA had highlighted in the CRL, as well as CMC related questions on extractable and leachable data provided in the NDA. Based upon the discussion with the FDA as reflected in the official meeting minutes, Recro anticipates resubmitting the IV meloxicam NDA by the end of September. The NDA resubmission will incorporate revised language relating to the product label and, additional information relating to extractable and leachable items.

"We are pleased with the constructive nature of our interactions with the FDA regarding IV meloxicam, and we expect to resubmit the NDA for IV meloxicam by the end of September," said Gerri Henwood, President and Chief Executive Officer of Recro. "We remain fully committed to IV meloxicam and to bringing this new non-opioid treatment option for the management of moderate to severe pain to the physicians and patients who need it."

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 May 2018, Recro received a Complete Response Letter from the FDA regarding IV meloxicam which it is currently seeking to resolve. 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 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 complete response letter for IV meloxicam and the time frame associated with such resolution, including whether the FDA will require additional clinical studies and the time and cost of such studies; whether the Company will be able to prepare an amended new drug application (NDA) for IV meloxicam and, if prepared, whether the FDA will accept and approve the amended NDA and the labeling under any such approval; 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. 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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