March 22, 2019

Recro Pharma Receives Complete Response Letter from the FDA for Intravenous Meloxicam

Management to Host Conference Call and Webcast Today at 4:30 p.m. ET

MALVERN, Pa., March 22, 2019 (GLOBE NEWSWIRE) -- Recro Pharma, Inc. (Nasdaq:REPH), a revenue generating specialty pharmaceutical company focused on therapeutics for hospitals and other acute care settings, today announced it has received a second Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) Office of Drug Evaluation II regarding their New Drug Application (NDA) seeking approval for intravenous (IV) meloxicam for the management of moderate to severe pain.

“We are extremely disappointed with the receipt of a second CRL from the FDA,” said Gerri Henwood, President and Chief Executive Officer of Recro Pharma. “We remain steadfast in our belief that IV meloxicam holds significant potential as a treatment option for moderate to severe pain in multiple clinical settings and remain committed to pursuing a path to regulatory approval. We are dedicated to bringing this and other non-opioid pain products to the market to help address the crippling opioid epidemic our country currently faces, as we believe they are an important tool for patients and physicians to safely and effectively manage pain in multiple clinical settings. We intend to work closely with the FDA to determine the best path forward to obtain approval for IV meloxicam.”

The FDA’s comments in the CRL focused on onset and duration of IV meloxicam, noting that the delayed onset fails to meet the prescriber expectations for intravenous (IV) drugs. The CRL also cited regulatory concerns about the role of IV meloxicam as a monotherapy in acute pain, as well as how it would meet patient and prescriber needs in that setting, given the FDA's interpretation of the clinical trials data. The company strongly disagrees with FDA's interpretation and its views on the clinical utility of IV meloxicam in the acute pain setting. The FDA did not identify any CMC issues in this CRL.

Recro intends to continue to pursue regulatory approval for IV meloxicam and will request a meeting with the FDA and work closely with them to resolve these issues.

Conference Call and Webcast

Recro Pharma management will be hosting a conference call and webcast today beginning at 4:30 p.m. ET. To access the conference call, please dial (844) 243-4691 (local) or (225) 283-0379 (international) at least 10 minutes prior to the start time and refer to conference ID 8067497. A webcast will be available in the investor relations section of the Company's website, www.recropharma.com. A live audio webcast of the call will be available under "Events" in the Investor section of the Company's website, https://ir.recropharma.com/events. An archived webcast will be available on the Company's website approximately two hours after the event and will be available for 30 days.

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 the 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 and 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," "may," "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 adequately resolve the deficiencies identified by the FDA in the second CRL for IV meloxicam, and the time frame associated with any such resolution, including whether the FDA will require additional clinical studies and the time and cost of such studies; whether the Company will prepare an amended new drug application (NDA) for IV meloxicam and, whether the FDA will accept and approve any such resubmitted NDA and the labeling under any such approval; with regard to our clinical trial results, whether there may be changes in the interpretation by the FDA of the data of our clinical trials; with regard to the potential commercial opportunity of IV meloxicam, whether any FDA approval of IV meloxicam will include labeling restrictions and the potential that IV meloxicam does not receive regulatory approval, does not receive reimbursement by third party payors or that a commercial market for IV meloxicam does not develop. 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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