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Recro Pharma Announces FDA Acceptance for Review of New Drug Application for IV Meloxicam 30mg

MALVERN, Pa., Sept. 28, 2017 (GLOBE NEWSWIRE) -- Recro Pharma, Inc. (Nasdaq:REPH), a revenue generating specialty pharmaceutical company focused on therapeutics for hospital and other acute care settings, today announced that the U.S. Food and Drug Administration (FDA) has accepted for review its New Drug Application (NDA) for intravenous (IV) meloxicam 30mg for the management of moderate to severe pain.

“The acceptance for review of the IV meloxicam 30mg NDA marks an important milestone in our effort to bring new therapeutics to patients and to the physicians who treat them,” said Gerri Henwood, President and Chief Executive Officer of Recro Pharma.

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 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 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. In addition, 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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