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Recro Announces Expansion of CDMO Service Capabilities

MALVERN, Pa., Oct. 01, 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 opening of an expanded 24,000 square foot GMP development and high potency product services facility in Gainesville, GA.

The new site, which is near the existing 97,000 square foot, DEA-licensed CDMO facility, houses an expanded development space focused on creating unique oral dosage forms, solving formulation, process and analytical issues, as well as providing additional capacity for clinical trial supply manufacturing and related services. In addition, the expanded facility has specialized space dedicated to the development and GMP manufacturing of high potency products. The new development facility is currently operational, and the high potency GMP suite will be operational shortly.

“Pharmaceutical companies increasingly need partners with specialized expertise in addressing their formulation and manufacturing challenges and this expansion of our CDMO facilities is in response to the increased demand we are seeing from our clients,” said Gerri Henwood, President and Chief Executive Officer of Recro Pharma. “For several years the Recro team has demonstrated its expertise in GMP drug manufacturing and development, offering our clients the highest quality services and technical standards. We believe these additional facilities and capabilities will allow us to provide a broader range of high quality services, both to our existing customers, as well as to new potential clients and partners.”

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 (CRL) 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 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.

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 CRL for IV meloxicam; whether the FDA will accept and approve the Company's amended new drug application (NDA) for IV meloxicam and, if approved, the labeling under any such approval; if the FDA does not accept the Company's amended NDA, the time frame otherwise associated with resolving the deficiencies identified by the FDA in the CRL and whether the FDA will require additional clinical studies to support the approval of IV meloxicam and the time and cost of such studies; 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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