Recro Pharma Announces Publication of Phase III IV Meloxicam Abdominoplasty Data in Plastic and Reconstructive Surgery Global Open Journal

MALVERN, Pa., June 26, 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 previously reported Phase III clinical data for intravenous (IV) meloxicam for the treatment of pain following abdominoplasty surgery. The article, titled “Efficacy and Safety of Intravenous Meloxicam in Subjects with Moderate to Severe Pain Following Abdominoplasty,” was published online in the Plastic and Reconstructive Surgery Global Open (PRS Global Open).

“The results of Recro’s Phase III trial evaluating IV meloxicam for the treatment of pain following abdominoplasty surgery detailed in this article demonstrate the efficacy and favorable safety profile of IV meloxicam,” said Stewart McCallum, M.D., Chief Medical Officer of Recro Pharma. “As a long-acting, non-opioid option, IV meloxicam’s differentiated profile has the potential to become a valuable alternative for patients and physicians in the management of moderate to severe pain.”

The Phase III, multi-center, randomized, double-blind, placebo-controlled trial (n=219) was designed to evaluate the efficacy and safety of IV meloxicam 30mg for the management of moderate to severe pain following abdominoplasty surgery. The primary efficacy endpoint was Summed Pain Intensity Difference (SPID) over 24 hours (SPID24). IV meloxicam 30mg achieved a statistically significant difference in SPID24 (p=0.0145) as compared to placebo, as well as statistically significant differences over placebo in SPID values at other times and intervals (SPID12, SPID48, SPID24-48), among other key secondary endpoints. Additionally, IV meloxicam 30mg was associated with a reduction in the number of subjects receiving opioid rescue medication during hours 24 to 48 and the total number of doses of opioid rescue analgesia. IV meloxicam 30mg was well tolerated, with the numbers and frequencies of adverse events similar 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 once a day 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. As injectable meloxicam is in the non-opioid class of drugs, if approved, 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 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 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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