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Recro Pharma Initiates Pivotal Phase III Clinical Trial of IV Meloxicam for Acute Postoperative Pain

MALVERN, Pa., Jan. 27, 2016 (GLOBE NEWSWIRE) -- Recro Pharma, Inc. (Nasdaq:REPH), a revenue generating specialty pharmaceutical company developing multiple non-opioid therapeutics for the treatment of pain, today announced that the first patient was dosed in the pivotal Phase III clinical trial evaluating intravenous (IV) meloxicam (N1539) for acute postoperative pain in patients following "mini" abdominoplasty surgery.

In this multicenter, randomized, double-blind, placebo-controlled clinical trial, IV meloxicam's efficacy and safety will be evaluated in the management of postoperative pain following abdominoplasty surgery, a representative soft tissue surgery. Approximately 200 patients will be assigned randomly to a postoperative regimen of IV meloxicam (30mg) or placebo in a 1:1 ratio, once every 24 hours for up to 3 doses following surgery. The primary efficacy endpoint of this Phase III study is the summed pain intensity difference over the first 24 hours (SPID24) compared to placebo. Recro expects to report top-line results from this Phase III study by year end 2016.

"Given the consistent encouraging clinical data from multiple Phase II trials in highly relevant pain models including bunionectomy, hysterectomy, dental and laparoscopic abdominal surgeries showing clear analgesic effect, we look forward to completing this pivotal Phase III trial in patients following soft tissue surgery," said Gerri Henwood, Recro Pharma's President and Chief Executive Officer. "We expect to initiate a second pivotal Phase III trial in a hard tissue bunionectomy model in this quarter. The initiation of this late-stage trial is an important milestone for Recro Pharma and we look forward to providing updates on our progress."

Abdominoplasty/"mini" abdominoplasty surgery generally involves the removal of excess fat and skin and, in most cases, restores weakened or separated muscles from the abdominal area. According to the American Society for Aesthetic Plastic Surgery, abdominoplasty is among the top five most common cosmetic surgeries in the U.S., with more than 164,000 performed in 2014. Abdominoplasty surgery typically results in intense postoperative pain.

About IV/IM Meloxicam

Meloxicam is a long-acting, preferential COX-2 inhibitor that possesses anti-inflammatory, analgesic, and antipyretic activities, which are believed to be related to the inhibition of cyclooxygenase (COX) and subsequent reduction in prostaglandin biosynthesis. Meloxicam has been marketed by Boehringer Ingelheim Pharmaceuticals, Inc. since the 1990's as an oral agent, Mobic®. IV/IM meloxicam was designed using NanoCrystal® platform, a technology that enables enhanced bioavailability of poorly water-soluble drug compounds. Recro acquired IV/IM meloxicam from Alkermes in April 2015.

About Recro Pharma, Inc.

Recro Pharma is a revenue generating specialty pharmaceutical company developing multiple non-opioid therapeutics for the treatment of pain. Recro Pharma is currently developing IV/IM meloxicam, a proprietary, long-acting preferential COX-2 inhibitor for treatment of acute postoperative pain, and Dex-IN, a proprietary intranasal formulation of dexmedetomidine, for the treatment of peri-procedural pain. Both compounds have successfully completed Phase II clinical trials. As Recro Pharma's product candidates are not in the opioid class of drugs, the Company believes its candidates would avoid many of the side effects associated with commonly prescribed opioid therapeutics, such as addiction, constipation and respiratory distress, while maintaining analgesic effect.

Recro Pharma also owns and operates an 87,000 square foot, DEA-licensed facility that manufactures five commercial products and receives manufacturing revenues and royalties associated with the sales of these products.

Cautionary Statement Regarding Forward Looking Statements

This press release contains forward-looking statements that involve risks and uncertainties. Such forward looking statements reflect Recro Pharma'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 Pharma or its management, are intended to identify such forward-looking statements. These forward looking statements are based on information available to Recro Pharma as of the date of this press release and are subject to a number of risks, uncertainties, and other factors that could cause Recro Pharma's performance to differ materially from those expressed in, or implied by, these forward looking statements. Recro Pharma assumes no obligation to update any such forward-looking statements. Factors that could cause Recro Pharma's actual performance to materially differ from those expressed in the forward-looking statements set forth in this press release include, without limitation: results and timing of the clinical trials of IV/IM meloxicam and Dex-IN; the ability to obtain and maintain regulatory approval of IV/IM meloxicam and Dex-IN, and the labeling under any such approval; regulatory developments in the United States and foreign countries; the Company's ability to raise future financing for continued development; the Company's ability to pay its debt; 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 IV/IM meloxicam and Dex-IN. In addition, the forward looking statements in this press release should be considered together with the risks and uncertainties that may affect Recro Pharma's business and future results included in Recro Pharma's filings with the Securities and Exchange Commission at www.sec.gov. Recro Pharma assumes no obligation to update any such forward looking statements.

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