

May 18, 2017



Recro Pharma Presents Phase III Bunionectomy Clinical Data for IV Meloxicam at the American Pain Society 36th Annual Scientific Meeting

Poster Presentation Highlighting Clinical Performance of IV Meloxicam 30mg, Including Statistically Significant Differences in SPID48 and Numerous Other Rescue Use and Pain Relief Metrics

MALVERN, Pa., May 18, 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 the presentation of clinical data from its Phase III study evaluating intravenous (IV) meloxicam 30mg for the treatment of acute postoperative pain in patients following bunionectomy surgery, at the American Pain Society 36th Annual Scientific Meeting, taking place May 17-20, 2017, in Pittsburgh, PA. The poster presentation highlights the clinical performance of IV meloxicam 30mg, including achievement of the study's primary endpoint, a statistically significant difference in Summed Pain Intensity Difference (SPID) over the first 48 hours (SPID48) compared to placebo, along with detailed secondary endpoints and safety results.

"The detailed Phase III results presented at the American Pain Society annual meeting highlight the clinical performance of IV meloxicam 30mg and the key features it can offer clinicians who are seeking non-opioid pain relief alternatives for their patients recovering from surgery," said Stewart McCallum, M.D., F.A.C.S., Chief Medical Officer for Recro Pharma and co-author of the poster. "The data from this late-stage trial demonstrate that IV meloxicam 30mg provides rapid and sustained pain relief following bunionectomy surgery, a favorable safety and tolerability profile, and statistically significant differences in rescue use and numerous other pain relief metrics, including length of time to opioid rescue and number of patients utilizing opioid rescue analgesia, among others."

Gerri Henwood, President and Chief Executive Officer of Recro, commented, "These exciting data demonstrate the key clinical attributes of IV meloxicam 30mg and support its potential as a new, non-opioid pain treatment option. If approved, IV meloxicam will be the only intravenously administered, once-daily, non opioid pain product and we believe it will play a meaningful role in the physician's analgesic toolkit. The data from this pivotal clinical trial in bunionectomy, together with the positive results from our Phase III trial in patients following abdominoplasty surgery and the positive Phase III safety trial results reported last week, will form the basis of a New Drug Application (NDA) for IV meloxicam 30mg for the treatment of moderate-to-severe pain, which we plan to file with the U.S. Food and Drug

Administration during early third quarter 2017.”

Efficacy Results

In this multicenter, randomized, double-blind, placebo-controlled clinical trial, 201 patients were enrolled and randomly assigned to receive a postoperative regimen of IV meloxicam 30mg (bolus injection) or placebo in a 1:1 ratio, once every 24 hours for up to 3 doses following bunionectomy surgery, a representative hard tissue surgery. For the study's primary endpoint, there was a statistically significant difference in SPID48 favoring IV meloxicam 30mg over placebo ($p=0.0034$).

The study also achieved statistical significance for 15 secondary endpoints. IV meloxicam 30mg demonstrated statistically significant differences in SPID6 ($p=0.0153$), SPID12 ($p=0.0053$), SPID24 ($p=0.0084$), SPID24-48 ($p=0.0050$). Statistically significant differences favoring IV meloxicam 30mg over placebo were also achieved for time to first use of rescue analgesia ($p=0.0076$), number of patients utilizing rescue analgesia at certain intervals (Hour 0-24, Hour 24-48, Hour 0-48), and number of rescue doses utilized per patient at certain intervals (Hour 0-24, Hour 24-48, Hour 0-48). The proportion of subjects reporting good or better (2+) pain control on the Patient Global Assessment (PGA) was significantly higher for IV meloxicam 30 mg compared to placebo at Hour 24 (57.9% vs. 43.3%; $p=0.0452$) and Hour 48 (84.2% vs. 65.6%; $p=0.0043$). The IV meloxicam 30 mg treatment group had a statistically significantly greater number of subjects experiencing $\geq 30\%$ improvement at Hour 6 ($p=0.0451$) and Hour 24 ($p=0.0107$), and $\geq 50\%$ improvement at Hour 24 ($p=0.0430$) compared to placebo.

Safety Results

Doses of IV meloxicam 30mg were well tolerated during the study, with the majority of subjects receiving 3 study doses (73%). Adverse events (AEs) were generally reported to be of mild intensity and occurred with greatest overall frequency in the placebo group. No deaths, serious adverse events (SAEs) or discontinuations due to an AE occurred in the IV meloxicam 30mg group. Two SAEs were reported in the placebo group; fracture of the bunionectomy repair secondary to trauma, and sudden death. AEs of special interest (including hepatic, renal, cardiovascular, bleeding, wound healing, and injection site events) were infrequent, with a greater incidence overall in the placebo group. There was no apparent trend in clinically meaningful abnormal laboratory results between the treatment groups. No trends for changes in vital signs or ECGs were observed.

A downloadable copy of the poster can be accessed by visiting the “Investors” section of the Recro Pharma website and by clicking “Presentations.”

Details for the poster presentation at APS 2017:

Title: Efficacy and Safety of N1539, Intravenous Meloxicam, in a Phase 3 Study of Subjects with Moderate to Severe Pain following Bunionectomy

Presenter: Richard Pollak, D.P.M., M.S., Endeavor Clinical Trials

Poster Board #: 391

Session: Phase I-III Clinical Trials and Pediatric Clinical Trials

Location: Convention Center, Halls A-C, Poster Section 33

Date and Time: Wednesday, May 17, 2017 at 4:15pm ET through Friday, May 19, 2017 at

1:30pm ET

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 a NanoCrystal[®] platform, a technology that enables enhanced bioavailability of poorly water-soluble drug compounds.

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 has successfully completed four Phase II clinical trials in the management of moderate to severe post-operative pain and two pivotal Phase III clinical efficacy trials in patients following bunionectomy and abdominoplasty surgeries, as well as a large double blind Phase III safety trial and 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 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: results and timing of the clinical trials of injectable meloxicam, the preparation and filing of other portions of the drug application, including CMC, the ability to obtain and maintain regulatory approval of injectable meloxicam and, and the labeling under any such approval, regulatory

developments in the United States and foreign countries; 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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