

October 10, 2017



Recro Pharma Presents Phase III IV Meloxicam Clinical Efficacy Data in Patients Following Abdominoplasty at the 2017 American Society of Plastic Surgeons Annual Meeting

IV Meloxicam 30mg Demonstrates Statistically Significant Reductions in Pain, Along with Reductions in Opioid Rescue Use and Improvements in Several Other Pain Relief Metrics

Selected as a "Top 6" Poster at the Meeting

MALVERN, Pa., Oct. 10, 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 an oral presentation highlighting clinical efficacy data from its Phase III study evaluating intravenous (IV) meloxicam 30mg for the treatment of acute postoperative pain in patients following abdominoplasty surgery. The poster was presented at Plastic Surgery The Meeting 2017, hosted by the American Society of Plastic Surgeons (ASPS), taking place October 6-10, 2017, in Orlando, FL. The poster, which was selected as a "Top 6" of the meeting, describes 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 24 hours (SPID24) compared to placebo, along with detailed secondary endpoints.

"The Phase III results presented this year at Plastic Surgery The Meeting demonstrate the efficacy of IV meloxicam 30mg, including significant reductions in pain, as evidenced by SPID24, meaningful reductions in opioid rescue use and improvements across numerous other pain relief metrics," said Stewart McCallum, M.D., F.A.C.S., Chief Medical Officer of Recro Pharma and co-author of the poster. "On the safety front, IV meloxicam 30mg continues to demonstrate a favorable safety and tolerability profile with a low incidence of adverse events (AEs), serious AEs and infusion events. We believe these results demonstrate IV meloxicam 30mg's ability to provide rapid and durable pain relief following abdominoplasty surgery and support its potential to be an attractive non-opioid alternative for physicians and patients for the treatment of acute, postoperative pain."

IV meloxicam 30mg has successfully completed three Phase III trials, including two Phase III efficacy trials and one Phase III safety trial. The results from these studies, as well as results from four Phase II trials and other safety studies, comprised the NDA package for IV meloxicam 30mg that was accepted for review by the U.S. Food and Drug Administration in

September 2017.

Efficacy Results

In this multicenter, randomized, double-blind, placebo-controlled clinical trial, 219 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 abdominoplasty surgery, a representative soft tissue surgery. For the study's primary endpoint, there was a statistically significant difference in SPID24 favoring IV meloxicam 30mg over placebo ($p=0.0145$).

The study also achieved statistical significance for ten secondary endpoints. IV meloxicam 30mg demonstrated statistically significant differences in SPID12 ($p=0.0434$), SPID48 ($p=0.0040$), SPID12-24 ($p=0.0115$) and SPID36-38 ($p=0.0119$). Statistically significant differences favoring IV meloxicam 30mg over placebo were also achieved for the number of rescue doses utilized per subject in each assessed study interval (Hour 0-24, Hour 24-48 and Hour 0-48; $p<0.05$). Kaplan-Meier estimates of median time to perceptible pain relief were significantly shorter for the IV meloxicam 30mg arm vs. placebo (0.76 vs. 1.28 hours, $p=0.005$). A statistically significant improvement in Patient Global Assessment (PGA) was observed for IV meloxicam 30mg compared to placebo at Hour 48 ($p=0.0027$). A significantly higher proportion of patients reporting a $\geq 30\%$ improvement over the first 24 hours following treatment with IV meloxicam 30mg (71.8%) compared to placebo (56.9%; $p=0.0178$).

Safety Results

IV meloxicam 30mg was well tolerated during the study, with the majority of subjects receiving three study doses (79.1%). Adverse events (AEs) were generally reported to be of mild intensity and occurred with the greatest overall frequency in the placebo group. No deaths or discontinuations due to an AE occurred in the IV meloxicam 30mg group. Four subjects experienced serious adverse events (SAEs) in the study (one IV meloxicam 30mg, three placebo): two events of post procedural haemorrhage (one IV meloxicam 30mg and one placebo); one event of post procedural pulmonary embolism (placebo) and one event of postoperative wound infection (placebo). 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. No trends for changes for vital signs or ECGs were observed.

Details for the Oral Presentation at Plastic Surgery The Meeting:

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

Location: ASPS Exhibit Hall Center Stage

Date and Time: Monday, October 9, at 11:45 am ET through 1:15 pm ET

A downloadable copy of the poster can be accessed by visiting the "Investors" section of the [Recro Pharma website](#) and clicking "Presentations".

For more information on Plastic Surgery The Meeting, visit: www.plasticsurgerythemeeting.com.

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 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 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. 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.

CONTACT:

Investor Relations Contact:
Argot Partners
Susan Kim/Natalie Wildenradt
(212) 600-1902
susan@argotpartners.com
natalie@argotpartners.com

Recro Pharma, Inc.
Michael Celano
(484) 395-2413
mcelano@recropharma.com

Media Contact:
Argot Partners
Eliza Schleifstein
(973) 361-1546
eliza@argotpartners.com



Source: Recro Pharma, Inc.