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Recro Pharma Provides Clinical Strategy Update Following Interim Analysis for Phase IIb Clinical Trial of Dex-IN

Analgesia in a subset of patients (50%), suggests therapeutic potential for Dex-IN in Post Op Day 1

Trial not expected to reach statistical significance as single agent on Post Op Day 0

Company to launch new study of Dex-IN 50 mcg in Post Op Day 1 bunionectomy model in Q4 2014; top line results estimated mid-year 2015

MALVERN, Pa., Sept. 4, 2014 (GLOBE NEWSWIRE) -- Recro Pharma, Inc. (Nasdaq:REPH), a clinical stage specialty pharmaceutical company developing non-opioid therapeutics for the treatment of pain, initially for acute pain following surgery, announced a clinical strategy update following findings from a prespecified interim analysis conducted on the initial half of patients who completed enrollment in the Company's REC-13-012 trial. The trial is a double blind, placebo-controlled study of intranasal dexmedetomidine, Dex-IN, in the treatment of acute post-operative pain following bunionectomy surgery on Post Op Day 0. While analgesia and a reduction in opioid use were observed in a subset of patients, the study is not expected to reach statistical significance in its current design. As a result, the Company plans to close this study and launch a revised study starting in Q4 2014. The Company will evaluate Dex-IN 50 mcg versus placebo in management of post-op pain starting Post Op Day 1 after bunionectomy surgery. Note that there were no serious adverse events observed in the REC-13-012 trial.

"There remains a significant unmet medical need for opioid-sparing analgesics, a need which we continue to believe may be addressed with Dex-IN," said Gerri Henwood, Recro Pharma's President and Chief Executive Officer. "Observations from an interim analysis of the REC-13-012 trial, however, suggest that the current study design will not allow us to reach statistical significance for single agent Dex-IN in a bunionectomy pain model starting on Post Op Day 0. That said, analgesia and corresponding reduction in opioid use, observed in a subset of patients, suggest that Dex-IN may serve as an effective pain management tool in a Post Op Day 1 bunionectomy study model. Based on what we know about the trajectory of pain, together with these observations, which confirm our earlier trial results and demonstrate efficacy for the first time in acute post-op pain, we believe that a study of 50 mcg Dex-IN in a Post Op Day 1 setting is the best path forward."

The interim analysis was based on the primary endpoint, SPID48 (summed pain intensity difference over 48 hours). This preplanned interim analysis was designed to allow for possible sample size adjustment. The results of the interim analysis (n=68, approximately 22

patients per group) revealed that the efficacy of Dex-IN as a stand alone drug was not sufficient to manage severe pain in bunionectomy on post operative day zero, Post Op Day 0. As a result, increased sample size is unlikely to be an effective modification of the trial.

In the interim analysis, the Company observed in patients with baseline pain intensity scores of ≤ 6 (N=34) that pain was more effectively managed on Post Op Day 0, as seen in the separation of scores between Dex-IN 50 mcg and Placebo (Table 1). In addition, based on an understanding of the trajectory of pain, it is recognized that pain on Post Op Day 0 is generally escalating, while pain on Post Op Day 1, or the day after surgery, is generally stable or declining. Based on the input from the Company's advisors, the results of the interim analysis and subset analyses, the information suggests that a post-operative pain management study in patients who initiate study treatment on Post Op Day 1 would be more effective than the current study design. The following table sets forth SPID48 scores from the interim analysis.

Table 1: SPID48
(In 34 patients with baseline pain intensity ≤6 and who completed 48 hour pain assessments)

	Dex-IN 50 mcg (n=12)	Dex-IN 35 mcg (n=9)	Placebo (n=13)
Mean (SD)	48.67 (76.938)	-9.67 (70.273)	-10.60 (90.997)
Effect size[1]	0.701	0.012	--

[1]Effect size quantifies the magnitude of the difference between two treatment groups (e.g., Dex-IN 50 mcg and placebo). An effect size of greater than 0.5 is typically considered good.

In addition, in this same population, opiate consumption (IV morphine and oral oxycodone) was reduced by approximately 50% versus placebo (Table 2). The following table sets forth the Rescue Medication used by patients in this population.

Table 2: Amount of Rescue Medication Used (morphine equivalence)[2]
(in 34 patients with baseline pain intensity ≤6 and who completed 48 hour pain assessments)

Mean consumption – Mean (SD)		
Dex-IN 50 mcg (n=12)	Dex-IN 35 mcg (n=9)	Placebo (n=13)
5.83 (6.793)	10.67 (9.487)	11.85 (7.186)

[2]This trend was consistent for observation of morphine use (mg) and oxycodone use (mg).

Based on these observations, the input of Recro Pharma's advisors in post-operative pain, and results observed in earlier Dex pain studies, the Company believes that an effective clinical strategy going forward is to study Dex-IN 50 mcg versus placebo in the management of post-operative pain starting on Post Op Day 1 after bunionectomy surgery. The Company expects such a study would enroll between 150 and 200 subjects, and is targeting initiation in Q4 2014, with top line results estimated to be available mid-year 2015.

About Recro Pharma, Inc.

Recro Pharma is a clinical stage specialty pharmaceutical company developing non-opioid, non-addictive therapeutics for the treatment of pain, initially for acute pain following surgery. Recro Pharma's lead product candidate, Dex-IN, is a proprietary intranasal formulation of dexmedetomidine and has completed a placebo controlled, proof of concept Phase Ib trial demonstrating effective pain relief. 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. If approved, Dex-IN would be the first and only approved acute pain drug in its class of drugs.

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 operating results, 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 actual results, performance, prospects, and opportunities 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 results to materially differ from those expressed in the forward-looking statements set forth in this press release include, without limitation: the results and timing of clinical trials of Dex-IN and any future clinical and preclinical studies; the ability to obtain and maintain regulatory approval of product candidates, 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 performance of third-party suppliers and manufacturers; the company's ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection; the successful commercialization of the company's product candidates; and the successful implementation of the company's strategy. 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.

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