FDA Grants Appeal to Recro Pharma for IV Meloxicam New Drug Application

Received Positive Response from FDA Regarding IV Meloxicam Formal Dispute Resolution Request

Company Remains on Track to Execute Spin Out of Acute Care Business Segment During the Fourth Quarter of 2019

MALVERN, Pa., Oct. 31, 2019 (GLOBE NEWSWIRE) -- Recro Pharma, Inc. (NASDAQ:REPH), a specialty pharmaceutical company with a high-performing revenue generating contract development and manufacturing (CDMO) division, today announced that it has received a written decision from the U.S. Food and Drug Administration (FDA) granting its appeal of the Complete Response Letter relating to the New Drug Application (NDA) seeking approval for intravenous (IV) meloxicam.

The FDA’s letter states that the appeal was granted “specific to the request...that the NDA provides sufficient evidence of effectiveness and safety to support approval.” The letter also states that “before IV meloxicam can be approved and legally marketed, agreed-upon labeling (prescribing information) must be negotiated with the Division.”

The Company is now in the process of preparing a comprehensive response to the FDA that includes proposed labeling that aligns with the FDA guidance received in the written decision letter and provides the relevant evidence from the filed NDA to ensure safe and effective use of IV meloxicam by prescribers.

“This positive response is very good news for Recro and the patients and providers who will benefit from the availability of this product,” said Gerri Henwood, Recro Pharma's President and Chief Executive Officer. “We are grateful for the expert advice we received from our advisors as well as for the time and attention of the FDA in this matter.”

The Company continues to expect that the spin out of the Recro Pharma Acute Care segment into an independently traded company will proceed as planned, and is expected to be concluded during the fourth quarter of 2019.

About IV Meloxicam

The active ingredient in Recro’s investigational drug is meloxicam, a long-acting, preferential COX-2 inhibitor that exhibits analgesic, anti-inflammatory and antipyretic activities, which are believed to be related to the inhibition of cyclooxygenase (COX) and subsequent reduction in prostaglandin biosynthesis. Recro’s 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 pharma services and pharmaceutical company that operates through two business segments, a revenue-generating contract development and manufacturing, or CDMO, segment, located in Gainesville, GA and an Acute Care segment primarily focused on products for the hospital and other acute care settings. The Company’s CDMO segment leverages its formulation expertise to develop and manufacture pharmaceutical products using its proprietary delivery technologies and other manufacturing services for commercial and development-stage 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 segment.

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," "may," "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 complete the spin of its Acute Care business, the Company’s ability to execute its strategy for further development and commercialization of IV meloxicam, the Company’s ability to execute its strategic initiatives, the Company’s ability to adequately resolve the outstanding labeling issues with the FDA for IV meloxicam, and the time frame associated with any such resolution; the Company’s ability to raise future financing for continued product development and IV meloxicam commercialization; with regard to the Company’s clinical trial results, whether there may be changes in the interpretation by the FDA of the data of the Company’s clinical trials and the length, cost and uncertain results and timing of our ongoing clinical trials; with regard to the potential commercial opportunity of IV meloxicam, whether any FDA approval of IV meloxicam will include labeling restrictions and the potential that IV meloxicam does not receive regulatory approval or does not receive reimbursement by third party payors, that IV meloxicam is not accepted by the medical community, including physicians, patients, health care providers and hospital formularies or that a commercial market for IV meloxicam does not develop; the Company’s ability to manage costs and execute on its operational and budget plans, the Company’s ability to achieve its financial goals, including financial guidance, the Company’s ability to pay its debt under its credit agreement; the Company’s ability to maintain relationships with CDMO commercial partners; 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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