

SoluMatrix[®] Meloxicam Demonstrates Significant Efficacy at 30 Percent Lower Doses in the Treatment of Osteoarthritis

- Phase 3 Data Presented at EULAR 2014 -

PHILADELPHIA, June 12, 2014 — Iroko Pharmaceuticals, LLC, a global specialty pharmaceutical company dedicated to advancing the science of analgesia, today will present Phase 3 results that showed osteoarthritis (OA) patients treated with investigational SoluMatrix[®] meloxicam 5 mg and 10 mg, a low dose nonsteroidal anti-inflammatory drug (NSAID), reported significantly greater pain relief compared with placebo¹. These data are being presented at the 2014 European League Against Rheumatism (EULAR) Annual European Congress of Rheumatology in Paris, France.

“Osteoarthritis is one of the most common causes of disability², and inadequate pain control can lead to joint stiffness that may impair mobility for patients,” said Dr. Roy Altman, Professor of Medicine in Rheumatology at UCLA and lead study author. “Clinicians have an urgent need for new osteoarthritis treatments that can offer reduced systemic exposure when taken over a long period of time, while also helping to restore some of the loss of function due to the nature of this chronic condition. These data show SoluMatrix[®] meloxicam represents an important new step forward in fulfilling the unmet need for effective low dose treatment options for osteoarthritis.”

In this Phase 3, multi-center, double-blind and placebo-controlled study, 403 patients aged 40 and older with a clinical diagnosis of OA of the knee or hip were randomized to receive treatment with once-daily SoluMatrix[®] meloxicam 5 mg, SoluMatrix[®] meloxicam 10 mg, or placebo. The primary efficacy endpoint of the study was the mean change from baseline in the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain subscale score at week 12. Secondary efficacy endpoints included the Patient Global Impression of Change (PGIC), a patient reported outcome measure, as well as the amount of rescue medication (acetaminophen) used by each patient¹.

Results of the study found:

- At week 12, patients treated with SoluMatrix[®] meloxicam 5 mg (P = 0.0005) and 10 mg (P = 0.0059) achieved significantly greater pain relief as measured by the WOMAC pain subscale score compared with patients receiving placebo¹.
- Based on PGIC, significantly more patients reported their condition as “very much improved” or “much improved” versus “much worse” or “very much worse” following SoluMatrix[®] meloxicam 5 mg (P = 0.0049) or 10 mg (P = 0.0012) treatment compared with placebo¹.
- Patients in the SoluMatrix[®] meloxicam 5 mg (P = 0.006) and 10 mg (P = 0.0013) treatment groups used significantly less rescue medication compared with patients in the placebo group¹.
- The most frequently reported adverse events (occurring in > 2 percent of patients) in patients treated with SoluMatrix[®] meloxicam were diarrhea, headache and nausea¹.

“In this study, SoluMatrix[®] meloxicam was evaluated at doses that are 30 percent lower than currently available meloxicam products, indicating that it may be a valuable low dose treatment option for osteoarthritis pain,” said Dr. Clarence Young, Chief Medical Officer of Iroko Pharmaceuticals. “We look forward to continuing to evaluate SoluMatrix[®] meloxicam as part of our robust low dose NSAID portfolio, which includes two FDA-approved products and a number of investigational drugs in the pipeline.”

About Iroko Pharmaceuticals, LLC

Iroko is a global specialty pharmaceutical company, based in Philadelphia, dedicated to advancing the science of analgesia. The company develops and globally commercializes pharmaceutical products. Iroko is at the forefront of the development of SoluMatrix[®] NSAIDs – new low dose drug products based on existing NSAIDs – using iCeutica Inc.’s proprietary SoluMatrix Fine Particle Technology™ exclusively licensed to Iroko for NSAIDs. The first SoluMatrix[®] NSAID is available in pharmacies and a second was recently approved by FDA. For more information, visit www.iroko.com.

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¹ Altman, R., et. al., Lower-Dose SoluMatrix® Meloxicam: Efficacy and Safety in a Phase 3 Study in Adults with Osteoarthritis Pain. Final Poster Presentation for 2014 European League Against Rheumatism (EULAR) Annual European Congress of Rheumatology.

² Neogi, T., The epidemiology and impact of pain in osteoarthritis, Osteoarthritis and Cartilage, 2013. Pg. 1.