



Iroko Pharmaceuticals Announces Acceptance for NDA Filing of Lower Dose Submicron Diclofenac for the Treatment of Mild to Moderate Acute Pain in Adults

PHILADELPHIA, March 04, 2013 — [Iroko Pharmaceuticals, LLC](#), a Philadelphia-based pharmaceutical company focused on the development and commercialization of innovative therapeutic products, today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for lower dose submicron diclofenac, a non-steroidal anti-inflammatory drug (NSAID), with a proposed indication of treatment of mild to moderate acute pain in adults.

“The FDA’s acceptance of our first NDA filing for lower dose submicron diclofenac is an important milestone for Iroko,” said John Vavricka, President and CEO of Iroko Pharmaceuticals. “Our goal is to address the significant unmet need in pain management by bringing new options to patients and physicians. We look forward to working closely with the FDA during the review process.”

The lower dose submicron diclofenac NDA submission included data from a Phase 3 multi-center, randomized study conducted in 428 otherwise healthy adults who developed significant pain following surgery. Patients treated with lower dose submicron diclofenac (18mg and 35mg) experienced significant pain relief post surgery compared with placebo ($P=0.01$ and $P<0.001$ respectively). These data were presented at the 54th Annual Meeting of the American Headache Society last year.

“We are pleased with the pace of progress that Iroko continues to display,” said Osagie Imasogie, Iroko’s Chairman and Senior Managing Partner of Phoenix IP Ventures. “We look forward to the prospect of commercializing this product and the balance of our submicron NSAID franchise.”



About Lower Dose Submicron NSAIDs

The risk of adverse events, including ulcers, gastrointestinal bleeds¹, and cardiovascular events² associated with currently marketed NSAIDs is higher among patients receiving higher doses of NSAIDs and longer duration of treatment³. Iroko is at the forefront of the development of lower dose submicron NSAIDs – novel formulations of NSAIDs that are designed to potentially provide effective pain relief at lower doses than existing commercially available formulations. These lower dose submicron NSAIDs are being developed by Iroko, using iCeutica Pty Ltd's proprietary SoluMatrix™ technology, licensed to Iroko for exclusive use in NSAIDs. The SoluMatrix™ technology alters the pharmacokinetic absorption properties of NSAIDs by reducing drug particles to finer particles that are at least 10 times smaller than standard NSAID formulations, thereby enhancing drug dissolution and promoting absorption.

About Iroko Pharmaceuticals, LLC

Iroko is a pharmaceutical company focused on the development and commercialization of innovative therapeutic products. The company acquires, develops and maximizes the potential of currently marketed products on a global basis through focused selling and marketing efforts and product-life-cycle management activities including development of new formulations that meet patient needs. In addition to Iroko's marketed products which are marketed in 48 countries, the company has a robust pipeline of late-stage NSAID submicron technology candidates using the proprietary SoluMatrix™ platform. These submicron NSAIDs are being developed using iCeutica Pty Ltd's SoluMatrix™ technology, licensed to Iroko for exclusive use in NSAIDs. For more information, visit www.iroko.com.

About Phoenix IP Ventures

A fully-integrated Private Equity and Venture Capital Fund which specializes in life sciences, principally in the pharmaceutical sector, the Firm acquires intellectual property protected assets that meet its criteria for value maximization. Phoenix IP Ventures works in collaboration with major players in the financial community to scale its own proprietary investments in transactions identified and managed by the Firm.



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¹ Rahme E et. al. (2001 Aug). Cost of prescribed NSAID-related gastrointestinal adverse events in elderly patients. Br J Clin Pharmacol. 52(2): 185-192.

² Howes LG. (2007 Oct.) Selective COX-2 inhibitors, NSAIDs and cardiovascular events – is celecoxib the safest choice? Ther Clin Risk Manag, 3(5), 831-845

³ Risser A. (2009 Dec). NSAID Prescribing Precautions. Am Fam Physician. 80(12):1371-1378.