



## **Results from a Phase 3 Study Show Iroko's Investigational Submicron Indomethacin Provided Effective Pain Relief at Lower Doses**

### ***Second Phase 3 Study from Iroko's Lower Dose Submicron NSAID Pipeline Shows Positive Results***

PHILADELPHIA, PA, December 07, 2012 — Iroko Pharmaceuticals, LLC today announced that the Phase 3 study evaluating the company's investigational, lower dose submicron indomethacin in post-surgical acute pain met its primary endpoint of demonstrating significant pain relief compared with placebo. Full results from the study will be presented at a future medical meeting.

"Physicians continue to face the challenge of balancing efficacy with safety when treating patients with pain," stated Dr. Clarence Young, Chief Medical Officer of Iroko Pharmaceuticals. "These top line results lend further support to our novel approach to developing new NSAID formulations that may be able to do more with less, a concept that could represent a significant new development in the area of pain management."

In the Phase 3, multi-center study of lower dose submicron indomethacin, 462 patients were randomized to receive submicron indomethacin (40mg twice or three times daily, or 20mg three times daily), celecoxib (400mg loading dose; 200mg twice daily,) or placebo. All doses of submicron indomethacin met the primary objective of demonstrating significant improvement in pain relief as measured by the combined differences in pain intensity evaluated at intervals over 48 hours using a visual analog scale (VASSPID-48) in patients with acute pain.

"Our multiple lower dose submicron NSAID programs are aimed at applying scientific innovation to the management of pain, to offer patients and physicians much needed options," said John Vavricka, President and CEO of Iroko Pharmaceuticals. "Data from this study, together with positive results

announced earlier this year from our Phase 3 study of lower dose submicron diclofenac in acute pain, add further momentum to Iroko’s goal of leading meaningful progress in this underserved therapeutic area.”

“These results add to the body of data from our pipeline and represent an important milestone toward our vision of developing a unique pharmaceutical portfolio focused on pain management,” said Osagie Imasogie, Iroko Chairman and Senior Managing Partner of Phoenix IP Ventures.

### **About Lower Dose Submicron NSAIDs**

The risk of adverse events, including ulcers, gastrointestinal bleeds<sup>1</sup>, and cardiovascular events<sup>2</sup> associated with currently marketed NSAIDs is higher among patients receiving higher doses of NSAIDs and longer duration of treatment<sup>3</sup>. 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 using iCeutica Pty Ltd’s proprietary SoluMatrix™ technology, licensed to Iroko for exclusive use in NSAIDs. SoluMatrix™ 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 the 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 with several late-stage NSAID submicron technology candidates using the proprietary SoluMatrix™ platform. For more information, visit [www.iroko.com](http://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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<sup>1</sup> 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.

<sup>2</sup> 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

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