Novel, Submicron Particle, Lower-Dose Diclofenac Demonstrated Relief of Acute Pain in Phase 3 Study

Iroko to Present Pivotal Data of an Investigational Drug as Late-Breaker at American Headache Society Meeting

PHILADELPHIA, June 21, 2012 — Iroko Pharmaceuticals, LLC today announced Phase 3 study results that showed patients treated with the company's novel, submicron particle, lower-dose diclofenac (18mg and 35mg), a non-steroidal anti-inflammatory drug (NSAID), experienced significant pain relief post surgery compared with placebo (P=0.01 and P<0.001 respectively). The pain relief scores seen with submicron particle diclofenac 35mg were numerically higher than those seen with submicron particle diclofenac 18mg and the active control celecoxib. These data will be presented on Friday at the 54th Annual Meeting of the American Headache Society in Los Angeles.

In the 428 patient, multi-center, randomized, double-blind, active- and placebo-controlled, post-surgical pain model Phase 3 study, both the 18mg and 35mg doses of the novel, submicron particle, lower-dose diclofenac met the primary objective of demonstrating significant improvement in pain relief as measured by the combined differences in pain intensity measured at intervals over 48 hours using a visual analog scale (VASSPID-48) in patients with acute pain. Pain relief scores were 524 for submicron particle diclofenac 35mg, 393 for submicron particle diclofenac 18mg, and 390 for celecoxib. Subjects receiving submicron particle diclofenac capsules 35mg achieved pain relief (P= 0.009) during the first four hours after initiating oral treatment (TOTPAR-4). The incidence of adverse events was generally comparable across treatment groups; the most common adverse events for all treatment groups were post-procedural swelling, nausea and headache. A single serious adverse event, deep venous thrombosis, was reported in the study for one subject in the celecoxib treatment group.

"These pivotal data indicate that submicron particle diclofenac may provide effective pain relief at a lower dose while offering fast onset of action," stated Stephen Silberstein, Professor of Neurology and Director of the Jefferson Headache Center at Thomas Jefferson University. "In meeting this important

study objective, this newly formulated diclofenac could represent a meaningful advance in the management of pain."

"Since existing NSAIDs are often associated with serious dose-related safety concerns, a great need exists for new therapeutics that can provide relief from acute pain and contribute to overall management of pain at lower doses," stated Allan Gibofsky, Professor of Medicine and Public Health at Weill Medical College of Cornell University. "By changing the pharmacokinetic absorption properties of diclofenac through innovative technology, we may now be able to offer patients the possibility of achieving pain relief using lower doses of diclofenac."

"This study represents the first of several late-stage clinical programs we have initiated to address the continuing need in pain management, by using scientific innovation to optimize established therapeutics," said Dr. Clarence Young, Chief Medical Officer of Iroko Pharmaceuticals. "These results further our understanding of the therapeutic potential of submicron particle NSAIDs and provide strong rationale for our extensive research program."

Study Details

The study was a Phase 3 multi-center, randomized, double-blind, multiple-dose, parallel-group, active- and placebo-controlled study conducted in 428 otherwise healthy persons who underwent surgery (bunionectomy with placement of metal rods) under regional anesthesia, experiencing a pain intensity rating of ≥40mm on a 100mm visual analog scale (VAS) during the nine-hour period after anesthesia was discontinued. Participants in the study were randomly assigned to receive submicron particle, lower-dose diclofenac (18 or 35mg three times a day), celecoxib (400mg first loading dose; 200mg twice a day), or placebo. The primary endpoint was the sum of pain intensity differences measured using a visual analog scale at intervals during the first 48 hours after discontinuation of general anesthesia (VASSPID-48).

"These findings are a significant step toward our goal of becoming a leader in the area of pain management by offering innovative therapeutic solutions that meet the needs of physicians and patients," said Osagie Imasogie, Iroko Chairman and Senior Managing Partner of Phoenix IP Ventures.

About Submicron Particle, Lower-dose NSAIDs

The risk of adverse events, including ulcers, gastrointestinal bleeds[1], and cardiovascular events[2] associated with currently marketed NSAIDs is higher among patients receiving higher doses and longer duration of treatment[3]. Iroko is at the forefront of the development of submicron particle lower-dose NSAIDs – novel formulations of NSAIDs that are designed to potentially provide effective pain relief at lower doses than existing commercially available formulations. These submicron particle NSAIDs are being developed using iCeutica, Inc.'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 absorption properties.

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 sold in over 45 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**.**

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.