Iroko Pharmaceuticals Receives FDA Approval for ZORVOLEX™

First NSAID Developed Using SoluMatrix Fine Particle Technology™

Philadelphia, Pennsylvania, October 18, 2013 - Iroko Pharmaceuticals, LLC, a global specialty pharmaceutical company dedicated to advancing the science of analgesia, today announced that the U.S. Food and Drug Administration (FDA) has approved ZORVOLEX™ (diclofenac) capsules, a nonsteroidal anti-inflammatory drug (NSAID), for the treatment of mild to moderate acute pain in adults[1]. ZORVOLEX was approved at dosage strengths that are 20 percent lower than currently available diclofenac products. FDA approval of ZORVOLEX was supported by data from a Phase 3 multi-center, randomized study in which patients treated with ZORVOLEX reported significant pain relief compared with patients receiving placebo[2].

"The approval of ZORVOLEX is important news for patients and for physicians who need new options for effective pain relief, and is a significant milestone for Iroko," said John Vavricka, President and CEO of Iroko Pharmaceuticals. "This marks a major achievement towards our goal of applying new technology to existing NSAIDs in order to address unmet medical needs in analgesia."

ZORVOLEX was developed to address FDA's public health advisory recommending that NSAIDs be used at the lowest effective dose for the shortest duration of time consistent with individual patient treatment goals[3]. The risk of serious adverse events, including cardiovascular thrombotic events, myocardial infarction, stroke, gastrointestinal ulcers, gastrointestinal bleeds[4] and renal events such as acute renal failure[5] associated with NSAIDs is higher among patients receiving higher doses[6].

"Given the serious, dose-related safety concerns associated with traditional NSAIDs, there is a need for new NSAID treatment options that can provide acute pain relief with lower systemic exposure," said Dr. Clarence Young, Chief Medical Officer of Iroko Pharmaceuticals. "By altering the absorption properties of diclofenac using innovative technology, ZORVOLEX offers patients the prospect of pain relief at lower doses."

ZORVOLEX is the first and only NSAID developed using proprietary SoluMatrix Fine Particle Technology™.

ZORVOLEX contains diclofenac as submicron particles that are approximately 20 times smaller than their original size. The reduction in particle size provides an increased surface area, leading to faster dissolution.

"Whenever I prescribe any pain medication to my patients I am concerned about two things – how effective the medication will be and the adverse event profile. Thus, ZORVOLEX is a welcome new therapeutic option," said Allan Gibofsky, Professor of Medicine and Public Health at Weill Medical College of Cornell University.

"The approval of ZORVOLEX is extremely rewarding, and is the result of our hard work and dedication within Iroko to make a lower dose diclofenac available to patients and physicians," said Osagie Imasogie, Executive Chairman of the Board, Iroko Pharmaceuticals. "We look forward to progressing the rest of our lower dose NSAID portfolio."

About Iroko's Lower Dose NSAID Portfolio

The risk of serious adverse events, including cardiovascular thrombotic events, myocardial infarction, stroke, gastrointestinal ulcers, gastrointestinal bleeds,[7] and renal events such as acute renal failure[8] associated with NSAIDs is higher among patients receiving higher doses[9]. Iroko is at the forefront of the development of lower dose NSAIDs – new low dose medicines based on existing NSAIDs – using iCeutica Pty Ltd's proprietary SoluMatrix Fine Particle Technology™ exclusively licensed to Iroko for use in NSAIDs. For more information see **www.iroko.com**.

ZORVOLEX is indicated for the treatment of mild to moderate acute pain in adults.

Important Safety Information about ZORVOLEX

Cardiovascular Risk

Nonsteroidal anti-inflammatory drugs (NSAIDs) may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.

ZORVOLEX is contraindicated for the treatment of perioperative pain in the setting of coronary artery bypass graft (CABG) surgery.

Gastrointestinal Risk
NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events.

ZORVOLEX is contraindicated in patients with: a known hypersensitivity to diclofenac or its inactive ingredients; a history of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs.

ZORVOLEX should be used at the lowest effective dose for the shortest duration consistent with individual patient treatment goals.

Elevation of one or more liver tests may occur during therapy with ZORVOLEX. Physicians should measure transaminases (ALT and AST) periodically in patients receiving long-term therapy with ZORVOLEX. ZORVOLEX should be discontinued immediately if abnormal liver tests persist or worsen.

NSAIDS, including ZORVOLEX, can lead to the new onset or worsening of existing hypertension which may contribute to the increased incidence of cardiovascular events. Blood pressure should be monitored closely during treatment with ZORVOLEX. NSAIDs may diminish the antihypertensive activity of thiazides, loop diuretics, ACE inhibitors and angiotensin II antagonists.

Fluid retention and edema have been observed in some patients taking NSAIDs. ZORVOLEX should be used with caution in patients with fluid retention or heart failure.

Long-term administration of NSAIDs can result in renal papillary necrosis and other renal injury. ZORVOLEX should be used with caution in patients at greatest risk of this reaction, including the elderly, those with impaired renal function, heart failure, liver dysfunction, and those taking diuretics and ACE inhibitors. Treatment with ZORVOLEX in patients with advanced renal disease is not recommended. Anaphylactoid reactions may occur in patients with the aspirin triad or in patients without prior exposure to ZORVOLEX and should be discontinued immediately if an anaphylactoid reaction occurs.

NSAIDs can cause serious skin adverse events such as exfoliative dermatitis, Stevens - Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. ZORVOLEX should be discontinued if rash or other signs of local skin reaction occur.

Starting at 30 weeks gestation, ZORVOLEX and other NSAIDs should be avoided by pregnant women as premature closure of the ductus arteriosus in the fetus may occur.

Concomitant administration of diclofenac and aspirin or anticoagulants is not generally recommended because of the risk of increased GI bleeding higher than users of either drug alone.

Most common adverse reactions in clinical trials (incidence ≥2%) include: edema, nausea, headache, dizziness, vomiting, constipation, pruritus, flatulence, pain in extremity, and dyspepsia.

ZORVOLEX capsules do not result in an equivalent systemic exposure to diclofenac as other oral formulations. Therefore, do not substitute similar dosing strengths of other diclofenac products for ZORVOLEX.

Please see full **Prescribing Information** for additional important safety and dosing information.

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. In addition to the Iroko products that are marketed worldwide, the company has a robust pipeline of investigational lower dose NSAID products being developed using iCeutica Pty Ltd's proprietary SoluMatrix Fine Particle Technology™. For more information, visit **www.iroko.com**.

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[1] ZORVOLEX Prescribing Information.
[2] ZORVOLEX Prescribing Information.
[3] U.S. Food and Drug Administration. Public Health Advisory - FDA Announces Important Changes and Additional Warnings for COX-2 Selective and Non-Selective Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).
[4] 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.
[5] Annual Review of Medicine, Nonsteroidal Antiinflammatory Drugs and Renal Function. Vol. 35: 411-428. DOI: 10.1146/annurev.med.35.020184.002211.
[6] Risser A. (2009 Dec). NSAID Prescribing Precautions. Am Fam Physician. 80(12):1371-1378.
[7] 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.
[8] Annual Review of Medicine, Nonsteroidal Antiinflammatory Drugs and Renal Function. Vol. 35: 411-428. DOI: 10.1146/annurev.med.35.020184.002211.
[9] Risser A. (2009 Dec). NSAID Prescribing Precautions. Am Fam Physician. 80(12):1371-1378.