Iroko Pharmaceuticals Announces First International Launch of ZORVOLEX®

Iroko's First Low Dose NSAID Now Available for Acute and Chronic Pain Outside of the U.S.

PHILADELPHIA, May 14, 2015 — Iroko Pharmaceuticals Inc., a global specialty pharmaceutical company dedicated to advancing the science of analgesia, today announced that ZORVOLEX® (diclofenac) capsules, a nonsteroidal anti-inflammatory drug (NSAID), is now available in 18 mg and 35 mg dosage strengths by prescription in Lebanon. ZORVOLEX was approved by the Republic of Lebanon Ministry of Public Health (MOPH) as a new chemical entity in December 2014 for the treatment of mild to moderate acute pain in adults and osteoarthritis pain[1,2].

"We are pleased to announce that ZORVOLEX is now available in Lebanon for both acute and chronic pain conditions, providing a low dose treatment option to patients and prescribers in the country," said Osagie Imasogie, Executive Chairman of the Iroko Board and Chief Executive Officer. "This first international launch of ZORVOLEX demonstrates our commitment to working with global partners to commercialize ZORVOLEX, and marks an important step in bringing our low dose NSAIDs to patients around the world."

This approval was the result of a licensing agreement signed in late 2013 by Iroko Pharmaceuticals Inc. and Algorithm S.A.L. under which Algorithm obtained the exclusive rights to register and market ZORVOLEX in countries in the Middle East and North Africa (MENA). Algorithm is planning to submit product registration applications for ZORVOLEX to other countries across the MENA region this year and next.

"We are proud to partner with Iroko to make ZORVOLEX available in Lebanon and look forward to working towards bringing the product to other countries in the region," said Selim Ghorayeb, CEO of Algorithm.

ZORVOLEX is approved by the U.S. Food and Drug Administration (FDA) for the management of mild to moderate acute and osteoarthritis pain, and is available at pharmacies across the United States[3]. Iroko Pharmaceuticals, LLC, an affiliate of Iroko Pharmaceuticals Inc., will continue to retain all marketing rights to ZORVOLEX in the U.S.

Since late 2013, Iroko Pharmaceuticals Inc., has entered into strategic agreements with pharmaceutical companies worldwide, who are obtaining the exclusive rights to market ZORVOLEX within their regions, and

is in discussions with additional companies to bring ZORVOLEX to other international markets. Current agreements cover several countries in the MENA, Latin America and Asia-Pacific regions.

About ZORVOLEX

ZORVOLEX was developed to align with recommendations from FDA and several professional medical organizations that NSAIDs be used at the lowest effective dose for the shortest possible duration consistent with individual patient treatment goals. ZORVOLEX is the first FDA-approved low dose NSAID developed using proprietary SoluMatrix Fine Particle Technology™ and is now available by prescription. ZORVOLEX contains diclofenac as submicron particles that are approximately 10 times smaller than their original size. The reduction in particle size provides an increased surface area, leading to faster dissolution. In 2014, ZORVOLEX was shortlisted in the Best New Drug category for the 10th Annual SCRIP Awards, an award which recognizes excellence in pharmaceutical development. For more information, visit **www.ZORVOLEX.com**.

ZORVOLEX is indicated for the management of mild to moderate acute pain and osteoarthritis pain.

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 that is higher than in users of either drug alone.

Most common adverse reactions in clinical trials (incidence ≥2%) include: edema, nausea, headache, dizziness, vomiting, constipation, pruritus, diarrhea, flatulence, pain in extremity, abdominal pain, sinusitis, alanine aminotransferase increased, blood creatinine increased, hypertension, 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.

For more information, visit **www.ZORVOLEX.com.**

About Algorithm S.A.L.

Algorithm, a Lebanon-based pharmaceutical manufacturer, is actively present in the MENA region and Cyprus. Algorithm is dedicated to offering quality products, either under license from reputable international companies or developed by the company's product development team. The portfolio consists of innovative products as well as differentiated generics, focusing mainly on the following therapeutic areas: Cardiometabolic Diseases, Ortho-Rheumatology, Neurology, Onco-Hematology, Endocrinology, Uro-Gynecology, and Dermatology. For more information, visit **www.algorithm-lb.com/en_Home**.

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. ZORVOLEX is the first SoluMatrix® NSAID and is available in pharmacies; a second was approved by FDA. For more information, visit **www.iroko.com**.

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[1] Lebanon Ministry of Health Approval Document for ZORVOLEX 18 mg.
[2] Lebanon Ministry of Health Approval Document for ZORVOLEX 35 mg.
[3] Prescribing Information for ZORVOLEX, pg. 1.