



## **Iroko Pharmaceuticals Announces Additional International Licensing Agreement for ZORVOLEX®**

*Partnership with Litha Pharma Expands Potential Commercialization Opportunities to Countries in Africa*

PHILADELPHIA, May 6, 2015 — Iroko Pharmaceuticals Inc., a global specialty pharmaceutical company dedicated to advancing the science of analgesia, today announced the initiation of a licensing agreement with Litha Pharma Proprietary Limited, a subsidiary of Litha Healthcare Group (“Litha”) for the exclusive rights to market and sell ZORVOLEX® (diclofenac) capsules in specified countries in East and Southern Africa. Litha will be responsible for obtaining regulatory and pricing approval as well as provide marketing and distribution in countries including Angola, Botswana, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Republic of South Africa, Seychelles, Swaziland, Tanzania and Zambia.

“Our partnership with Litha marks the seventh international licensing agreement for ZORVOLEX, our first low dose NSAID developed with the SoluMatrix Fine Particle Technology™,” said Osagie Imasogie, Executive Chairman of the Board and Chief Executive Officer of Iroko Pharmaceuticals. “Through these agreements, Iroko has expanded potential commercialization opportunities for ZORVOLEX across five continents: North America, South America, Africa, Asia and Australia.”

ZORVOLEX is approved by the United States Food and Drug Administration (FDA) for the management of mild to moderate acute pain and osteoarthritis pain, and is available at pharmacies across the United States<sup>1</sup>. ZORVOLEX was also recently approved by the Republic of Lebanon Ministry of Public Health (MOPH) for these indications<sup>2,3</sup>.

“We are delighted to work with Iroko to make ZORVOLEX available in the 13 countries covered by this agreement and look forward to a fruitful partnership,” said Norbert Oppitz, Regional Vice President, Latin America, Africa and Export Markets for Endo International plc., holding company of Litha.

Current licensing agreements for ZORVOLEX cover countries in the Middle East North Africa (MENA) region, Australia and New Zealand, Indonesia, and countries in Latin America, including the Central America region, Colombia, Venezuela, Mexico and Brazil. Iroko is in discussions with additional potential distribution and



marketing partners in other international markets. Iroko Pharmaceuticals, LLC, an affiliate of Iroko Pharmaceuticals Inc., will continue to retain all marketing rights to ZORVOLEX in the U.S.

### **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](http://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  $\geq 2\%$ ) 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](http://www.ZORVOLEX.com)**.

### **About Litha Healthcare Group**

Litha is a diversified healthcare group providing services, products and solutions to public and private hospitals, pharmacies, general and specialist practitioners, as well as government healthcare programmes, headquartered in Midrand, South Africa.

Paladin Labs Inc., an indirect subsidiary of Endo International plc acquired all of the remaining shares in Litha in February 2015.

Litha's leadership team brings together a group of highly regarded professionals with many years of experience within the South African healthcare sector and now benefits from the expertise and product pipeline available through its holding company, Endo International plc.

Litha Healthcare Group's operations are focused on harnessing its unique product offering to achieve its company Mission of, "*actively participating in and contributing to the creation of a healthier society, through the provision of integrated healthcare.*"



Litha is an operating company of Endo International plc (NASDAQ: ENDP) (TSX: ENL), a global specialty healthcare company focused on improving patients' lives while creating shareholder value. Learn more at [www.endo.com](http://www.endo.com).

### **About Litha Pharma**

Litha Pharma is a division of Litha Healthcare Group and has been a key strategic area of growth for the Group since 2012 when it was acquired and merged with Pharmaplan. Litha Pharma has numerous license agreements, co-marketing and joint ventures with international healthcare companies and will continue to pursue additional opportunities that are a strategic fit. Access and ownership to product pipelines is an intrinsic part of its long-term strategy and Litha Pharma has many exciting new products in various stages of registration at the Medicines Control Council.

*Key therapeutic areas of focus include:*

Gastroenterology	Neurology
Urology	Dermatology
Psychiatry	Nephrology
Cardiology	Gynaecology
Ophthalmology	Allergology
ENT	Pain Management

### **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](http://www.iroko.com).

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SoluMatrix Fine Particle Technology™ is a trademark of iCeutica Inc., and the technology is licensed to Iroko for exclusive use in NSAIDs.

SoluMatrix® is a trademark of iCeutica Pty Ltd and is licensed to Iroko.

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<sup>1</sup> Prescribing Information for ZORVOLEX, pg. 1.

<sup>2</sup> Lebanon Ministry of Health Approval Document for ZORVOLEX 18 mg.

<sup>3</sup> Lebanon Ministry of Health Approval Document for ZORVOLEX 35 mg.