Iroko Pharmaceuticals Announces Eighth International Licensing Agreement for ZORVOLEX®

New Partnership Expands Commercialization Footprint for Low Dose NSAID

PHILADELPHIA, July 15, 2015 — Iroko Pharmaceuticals Inc., a global specialty pharmaceutical company dedicated to advancing the science of analgesia, today announced that it has entered into a licensing agreement with LABORATORIOS SAVAL S.A. for the exclusive rights to market and sell ZORVOLEX® (diclofenac) capsules, a nonsteroidal anti-inflammatory drug (NSAID), in an additional five countries in South America. LABORATORIOS SAVAL S.A. will be responsible for obtaining regulatory and pricing approval as well as provide marketing and distribution in Bolivia, Chile, Ecuador, Paraguay and Peru. Iroko has previously announced international licensing agreements for ZORVOLEX with other partners that cover the South American countries of Brazil, Colombia and Venezuela, as well as Mexico and countries in Central America.

"This agreement with LABORATORIOS SAVAL S.A. now means we have partnerships in more than 90 percent of South American territories for ZORVOLEX and will further expand the global reach of Iroko's first low dose SoluMatrix® NSAID," said Osagie Imasogie, Executive Chairman of the Board and Chief Executive Officer of Iroko Pharmaceuticals. "With the signing of this agreement, we now have the opportunity to introduce ZORVOLEX in more than 45 countries around the world."

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 U.S.[1] ZORVOLEX is also approved by the Republic of Lebanon Ministry of Public Health (MOPH) for these indications, and is now available in 18 mg and 35 mg dosage strengths by prescription[2,3].

"We are excited to be partnering with Iroko to bring this valuable treatment to South America, where effective low dose options are needed to treat patients suffering from acute and chronic pain conditions," said Emilio Saval, Chairman and Owner of LABORATORIOS SAVAL S.A. "We hope this partnership will lead to more patients gaining access to an innovative therapeutic treatment option."

Additional licensing agreements for ZORVOLEX cover countries across South America, as well as in the Middle East & North Africa (MENA) region, Southern African countries, Australia and New Zealand, and

Indonesia. 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**.

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 LABORATORIOS SAVAL S.A.

LABORATORIOS SAVAL S.A. is a family owned pharmaceutical company, with a long and successful history in Chile. During the last decade, LABORATORIOS SAVAL S.A. successfully extended its activities to various countries in Latin America, carrying the same corporate message, which has been its flag in every market: a broad range of products and services that contribute to people's well-being. Introducing innovative pharmaceutical products to the market is an important element of the corporate philosophy, which has guided the company throughout its impressive trajectory.

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 and is also available by prescription in the U.S. For more information, visit **www.iroko.com**.

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