Iroko Pharmaceuticals Gains Additional Patents for ZORVOLEX® and TIVORBEX™

PHILADELPHIA, April 8, 2015 — Iroko Pharmaceuticals, LLC, a global specialty pharmaceutical company dedicated to advancing the science of analgesia, today announced that two new patents have been issued by the United States Patent and Trademark Office (USPTO) for the company's FDA-approved low dose nonsteroidal anti-inflammatory drugs (NSAIDs). The first patent is a method of treatment patent for ZORVOLEX® (diclofenac) capsules 18 and 35 mg, and the second patent is for composition of matter of TIVORBEX™ (indomethacin) capsules 20 and 40 mg.

"We are proud to announce two additional patents granted through our ongoing partnership with iCeutica to cover our pipeline of low dose NSAIDs," said Osagie Imasogie, Executive Chairman of the Board and Chief Executive Officer of Iroko Pharmaceuticals. "Protecting the commercial prospects of our products is of utmost importance as we bolster our portfolio and continue our focus on providing doctors and patients with a new approach to managing both acute and chronic pain."

ZORVOLEX is approved by the U.S. 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. TIVORBEX is approved by FDA for the treatment of mild to moderate acute pain in adults.[1,2]

The term of the patents issued for ZORVOLEX and TIVORBEX expires no earlier than 2030. In addition, ZORVOLEX and TIVORBEX have three years of regulatory exclusivity from date of product approval through FDA's regulatory pathway. Both patents will be listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations publication, or Orange Book, which includes all FDA-approved drugs, as well as patents and exclusivity information associated with those drugs. Iroko and iCeutica continue to prosecute additional patent applications for these and other products in the Iroko portfolio of low dose SoluMatrix® NSAIDs.

About Iroko's SoluMatrix® NSAIDs

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. Iroko's portfolio includes ZORVOLEX® (diclofenac) capsules – the first NSAID developed using proprietary SoluMatrix Fine Particle Technology™ that is now available in pharmacies – and TIVORBEX™ (indomethacin) capsules. 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. TIVORBEX is approved by FDA for the treatment of mild to moderate acute pain in adults.[1,2]

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.**

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

Important Safety Information about TIVORBEX

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.

TIVORBEX 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.

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

TIVORBEX 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 NSAIDs, including TIVORBEX. Physicians should measure transaminases (ALT and AST) periodically in patients receiving long-term therapy with TIVORBEX. TIVORBEX should be discontinued immediately if abnormal liver tests persist or worsen.

NSAIDs, including TIVORBEX, 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 TIVORBEX. 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. TIVORBEX 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. TIVORBEX 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 TIVORBEX in patients with advanced renal disease is not recommended.

Anaphylactic reactions may occur in patients with the aspirin triad or in patients without prior exposure to TIVORBEX and should be discontinued immediately if an anaphylactic reaction occurs.

Indomethacin may aggravate depression, and other psychiatric disturbances, epilepsy, or parkinsonism, and should be used with caution in patients with these conditions. Indomethacin may cause drowsiness; therefore patients should be cautioned about engaging in activities requiring mental alertness and motor coordination. Discontinue TIVORBEX if severe central nervous system (CNS) adverse reactions develop.

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

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

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

Most common adverse reactions in clinical trials (incidence ≥2%) include: nausea, post procedural edema, headache, dizziness, vomiting, post procedural hemorrhage, constipation, pruritus, diarrhea, dyspepsia, post procedural swelling, presyncope, rash, upper abdominal pain, somnolence, generalized pruritus, hyperhidrosis, decreased appetite, hot flush, and syncope.

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. 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; TIVORBEX™ is approved by FDA. For more information, visit **www.iroko.com**.

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[1] Prescribing Information for ZORVOLEX, pg. 1

[2] Prescribing Information for TIVORBEX, pg. 1