



ROXRO ANNOUNCES FDA APPROVAL OF SPRIX™
(Ketorolac Tromethamine)

- First Non-narcotic Intranasal Analgesic for Moderate to Moderately Severe Pain -

MENLO PARK, CA (May 17, 2010) – ROXRO PHARMA, Inc. (www.roxropharma.com) announced today that the U.S. Food and Drug Administration (FDA) has approved SPRIX™ (ketorolac tromethamine) Nasal Spray, for the short-term (up to 5 days) management of acute moderate to moderately severe pain that requires analgesia at the opioid level. SPRIX is a prescription intranasal formulation of the analgesic ketorolac, a non-steroidal anti-inflammatory drug (NSAID), designed to provide ambulatory patients with a convenient, potent, and fast-acting option for acute moderate to moderately severe pain relief. Ketorolac tromethamine is a frequently administered non-narcotic injectable analgesic for moderately severe pain in U.S. hospitals today. The approval of SPRIX provides acute pain outpatients with a non-narcotic and easy-to-administer alternative to commonly prescribed opioids.

“The FDA approval of SPRIX provides an important new tool for physicians treating patients with moderate to moderately severe pain. This is particularly significant at a time when patients and physicians have become increasingly concerned with use of narcotic pain relievers,” said Roberto Rosenkranz, Chief Executive Officer of ROXRO. “Currently approved injectable forms of ketorolac are already well accepted by the physician community for in-hospital use, so we believe uptake of this more convenient form will be rapid.”

“SPRIX fills the need for a new non-opioid, non-injectable option for ambulatory pain control,” said Askomur Buvanendran, Director Orthopedic Anesthesia, Rush University Medical Centers, Chicago, IL “Because it minimizes the potential for abuse as well as the negative side effects associated with narcotic pain relievers while providing potent control of moderate to moderately severe pain at the opioid level. The convenient nasal spray formulation will also provide pain relief outside of the hospital setting.”

About SPRIX

SPRIX is a novel intranasal formulation of the potent non-steroidal anti-inflammatory drug (NSAID) ketorolac. Currently, ketorolac is most often administered in the hospital setting as an injection for the short-term treatment of moderately severe pain. Formulated as an easy-to-use spray, SPRIX is rapidly absorbed through the nasal mucosa, achieving peak blood levels as fast as an intramuscular injection of ketorolac. SPRIX has been studied in moderate to moderately severe pain, both alone and in combination with morphine. The New Drug Application package for SPRIX included data from more than 1,000 subjects and 14 clinical trials. SPRIX has been tested in four controlled efficacy studies, and met the primary efficacy endpoints in each trial. Phase 3 studies of adults who underwent elective abdominal or orthopedic surgery (n=300 and n=321) indicated that SPRIX provided a statistically significant greater reduction in the summed pain intensity difference, a commonly accepted measure of pain, over 48 hours as compared to those using placebo. SPRIX has also demonstrated a 26-36 percent reduction in morphine use by patients over a 48 hour period as compared with placebo.

Important Safety Information About SPRIX

WARNING: LIMITATIONS OF USE, GASTROINTESTINAL, BLEEDING, CARDIOVASCULAR, and RENAL RISK

- Limitations of Use – The total duration of use of SPRIX and other ketorolac formulations should not exceed 5 days.
- Gastrointestinal (GI) Risk – Ketorolac can cause peptic ulcers, GI bleeding, and/or perforation of the stomach or intestines, which can be fatal. SPRIX is CONTRAINDICATED in patients with peptic ulcer disease or history of GI bleeding.
- Bleeding Risk – SPRIX inhibits platelet function and is CONTRAINDICATED in patients with suspected or confirmed cerebrovascular bleeding, hemorrhagic diathesis, incomplete hemostasis, or high risk of bleeding.
- Cardiovascular (CV) Risk – NSAIDs may cause an increased risk of serious CV thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with CV disease or risk factors for CV disease may be at greater risk. SPRIX is CONTRAINDICATED for treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery.
- Renal risk – SPRIX is CONTRAINDICATED in patients with advanced renal impairment and in patients at risk for renal failure due to volume depletion.

Mild, transient nasal discomfort was the most frequently reported side-effect of SPRIX use. SPRIX is contraindicated in patients with known hypersensitivity or a history of allergic reactions to aspirin, ketorolac, other NSAIDs or EDTA; in patients at risk for GI bleeding; prior to major surgery or during the perioperative period in CABG surgery; in patients with advanced renal disease or volume depletion; patients with certain bleeding risk and during labor and delivery. SPRIX should not be used concurrently with probenecid or pentoxifylline. Treat patients for the shortest duration possible, and do not exceed 5 days of therapy with SPRIX. **See the full prescribing information for more details.**

About ROXRO

ROXRO PHARMA, Inc. is a late-stage specialty pharmaceutical company developing hospital strength acute pain products for convenient use by patients in the home setting. The company is led by a

seasoned management team that has discovered, developed and commercialized several pain and cardiovascular medicines that are widely prescribed today. www.roxropharma.com

Contact

Media:

Cory Tromblee

MacDougall Biomedical Communications

781-235-3060

ctromblee@macbiocom.com

ROXRO PHARMA, Inc.:

Gayle Mills

Chief Business Officer

ROXRO PHARMA, Inc.

(650) 322-4554