



## PRESS RELEASE

**FOR IMMEDIATE RELEASE**

**December 13, 2010**

### **Luitpold Pharmaceuticals, Inc. Acquires ROXRO PHARMA, Inc., a U.S. Company Developing Acute Pain Products**

Contact Information:

Walter Tozzi, RPh, MS, MBA

Sr. Director of Marketing & Professional Services

631-924-4000

**Shirley, N.Y. (December 13, 2010)** – Luitpold Pharmaceuticals, Inc. a New York based U.S. subsidiary of Daiichi Sankyo Co., Ltd. (Corporate Headquarters: Tokyo, Japan) announced today that it has signed a binding merger agreement with ROXRO PHARMA, Inc. (Roxro), a privately held U.S. specialty pharmaceutical company, developing products for the treatment of acute pain conditions. The financial terms of the acquisition were not disclosed.

In May of 2010, Roxro obtained FDA approval for SPRIX<sup>®</sup> (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<sup>®</sup> is a prescription intranasal formulation of the analgesic ketorolac tromethamine (previously marketed as Toradol<sup>®</sup> by Roche Laboratories), a non - steroidal anti - inflammatory drug (NSAID). SPRIX<sup>®</sup> is designed to provide ambulatory patients with a convenient, potent, and fast - acting option for acute moderate to moderately severe pain relief.

Mary Jane Helenek, president and CEO of Luitpold said, “We are pleased to be able to provide healthcare professionals with an important new non-narcotic analgesic to treat acute pain in ambulatory patients. We believe that SPRIX<sup>®</sup> will be highly complimentary to Luitpold’s existing product line and our continuing strategy to diversify our product portfolio and further grow our U.S. pharmaceutical business.”

“We are delighted that Luitpold will be marketing SPRIX<sup>®</sup>”, said Roberto Rosenkranz, chairman and CEO of Roxro Pharma, Inc. “We believe that Luitpold has the infrastructure, expertise and capabilities to successfully bring this novel treatment to patients with moderate to moderately severe acute pain.”

Luitpold’s legal and financial advisers on the transaction were Sheppard Mullin Richter and Hampton LLP and Aquilo Partners, L.P., respectively.

Roxro’s legal and financial advisers were Goodwin Proctor LLP and Lazard, respectively.

LUITPOLD PHARMACEUTICALS, INC. • ONE LUITPOLD DRIVE • PO BOX 9001 • SHIRLEY • NEW YORK 11967  
(631) 924-4000 • FAX: (631) 924-1731

## **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 nasal 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 patients with 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.

### **About Luitpold Pharmaceuticals, Inc.**

Luitpold Pharmaceuticals, Inc., headquartered in Shirley, NY, manufactures and distributes over 80 pharmaceutical products including Venofer<sup>®</sup> (iron sucrose injection, USP), the # 1 selling IV iron therapy in the U.S., through its human health subsidiary, American Regent, Inc. Luitpold Pharmaceuticals, Inc., a Daiichi Sankyo group company, also markets dental bone regeneration products and veterinary pharmaceuticals through its Osteohealth and Animal Health divisions. Daiichi Sankyo Company, Ltd., established in 2005 after the merger of two leading century-old Japanese pharmaceutical companies, is a global pharmaceutical innovator, continuously generating innovative drugs that enrich the quality of life for patients around the world.  
[www.luitpold.com](http://www.luitpold.com)

### **About ROXRO PHARMA, Inc.**

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](http://www.roxropharma.com)

[Click here](#) to see full prescribing information for more details or visit [www.sprx.com](http://www.sprx.com).