

For Immediate Release

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**Regency Therapeutics and Daiichi Sankyo Announce Launch and Commercial Availability of  
SPRIX® (ketorolac tromethamine) Nasal Spray**

Attached is the joint press release between Regency Therapeutics, a newly established division of Luitpold Pharmaceuticals, Inc., and its co-promotion partner, Daiichi Sankyo, Inc. which was issued on May 17, 2011. Both companies are subsidiaries of Daiichi Sankyo Co., Ltd.,



## PRESS RELEASE

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**May 17, 2011**

# **Regency Therapeutics and Daiichi Sankyo Announce Launch and Commercial Availability of SPRIX® (ketorolac tromethamine) Nasal Spray**

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**Shirley, NY and Parsippany, NJ (May 17, 2011)** – Regency Therapeutics, a newly established division of Luitpold Pharmaceuticals, Inc., and its co-promotion partner Daiichi Sankyo, Inc., announced today that they have launched SPRIX® (ketorolac tromethamine) Nasal Spray and that it is now commercially available. SPRIX® was approved by the U.S. Food and Drug Administration (FDA) in May 2010 for the short-term (up to 5 days) management of moderate to moderately severe pain that requires analgesia at the opioid level.

SPRIX® is a prescription intranasal formulation of the analgesic ketorolac tromethamine injection, a non-steroidal anti-inflammatory drug (NSAID). Ketorolac tromethamine injection is currently widely used in hospitals and was previously marketed in the U.S. as Toradol® by Roche Laboratories. More than 500 million injections have been administered in the U.S. since its introduction in 1990. With the launch of SPRIX®, this potent non-opioid pain reliever is now available in a convenient self-administered intranasal dosage form.

SPRIX® was developed by ROXRO PHARMA, Inc. ROXRO was acquired by Luitpold in December 2010. Luitpold Pharmaceuticals is a New York based U.S. subsidiary of Daiichi Sankyo Co., Ltd. (Corporate Headquarters: Tokyo, Japan).

SPRIX® is supplied in boxes containing five single-day nasal spray bottles. Each single-day nasal spray bottle is designed to administer precisely metered doses of 100µL (15.75 mg) of ketorolac tromethamine per spray and contains sufficient quantity to deliver eight sprays, for a total of 126 mg of ketorolac tromethamine. For adult patients < 65 years of age, the

recommended dosage is 31.5 mg (one 15.75 mg spray in each nostril) every six to eight hours. For patients  $\geq$  65 years of age, renally impaired patients, and patients less than 110 lbs, the recommended dosage is 15.75 mg (one 15.75 mg spray in only one nostril) every six to eight hours.

Mary Jane Helenek, President and CEO of Luitpold said, “We are pleased to be able to provide healthcare professionals with an important new non-opioid analgesic to treat moderate to moderately severe acute pain. We believe that SPRIX® (ketorolac tromethamine) Nasal Spray will be highly complementary to Luitpold’s existing product line and our continuing strategy to diversify our product portfolio and further grow our U.S. pharmaceutical business.”

Regency Therapeutics’ specialty sales force will market SPRIX® to hospitals, emergency medicine treatment centers, surgeons and other specialists. SPRIX® will also be marketed to dentists, oral surgeons and periodontists by Luitpold’s Osteohealth division. Through a pending co-promotion agreement, Daiichi Sankyo, Inc. will promote SPRIX® to primary care physicians.

“Given the wide variety of practitioners who prescribe acute pain relievers, we are fortunate that Daiichi Sankyo and Luitpold, another US-based Daiichi Sankyo Group company, can work together to broaden our reach and ensure all of the appropriate healthcare providers are educated about SPRIX, a well-established, non-narcotic analgesic in a new, intranasal delivery system. SPRIX® provides patients with opioid-level pain relief in a non-opioid compound,” said Greg Barrett, Vice President of Marketing, Daiichi Sankyo, Inc.

#### **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

SPRIX® is also contraindicated in patients with known hypersensitivity or history of asthma, urticaria, or other allergic-type reactions to aspirin, ketorolac, other NSAIDs or EDTA. However, anaphylactoid reactions may occur in patients with or without a history of allergic reactions to aspirin or NSAIDs. SPRIX® is contraindicated in patients as a prophylactic analgesic prior to major surgery; or in labor, delivery, or nursing mothers.

SPRIX® (ketorolac tromethamine) should not be used concomitantly with IM/IV or oral ketorolac, aspirin, or other NSAIDs, or with probenecid or pentoxifylline.

Ketorolac can cause serious GI adverse events including bleeding, ulceration, and perforation. Elderly patients are at increased risk for serious GI events. Ketorolac can cause renal injury. SPRIX® Nasal Spray should be used with caution in patients with advanced renal disease or patients at risk for renal failure due to volume depletion and should be used with caution in patients taking diuretics or ACE inhibitors. NSAIDs can cause serious dermatologic adverse reactions such as exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, which can be fatal. SPRIX® should be discontinued immediately in patients with skin reactions. During pregnancy, use of SPRIX® beyond 30 weeks gestation can cause premature closure of the ductus arteriosus, resulting in fetal harm (Pregnancy Category D). Prior to 30 weeks gestation, SPRIX® should be used during pregnancy only if potential benefit justifies the potential risk to the fetus (Pregnancy category C). Do not use SPRIX® in patients for whom hemostasis is critical.

Fluid retention and edema have been observed in patients taking NSAIDs. SPRIX® should be used with caution in patients with cardiac decompensation or similar conditions.

The most common adverse reactions (incidence  $\geq$  2%) in patients treated with SPRIX® and occurring at a rate at least twice that of placebo are nasal discomfort, rhinalgia, increased lacrimation, throat irritation, oliguria, rash, bradycardia, decreased urine output, increased ALT and/or AST, hypertension, and rhinitis.

Treat patients for the shortest duration possible, and do not exceed 5 days of therapy with SPRIX®.

Please visit <http://www.sprix.com/docs/full-prescribing-information.pdf> to see the full prescribing information for SPRIX® or visit [www.sprix.com](http://www.sprix.com).

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

Luitpold Pharmaceuticals, Inc., a Daiichi Sankyo Group Company, headquartered in Shirley, NY, manufactures over 80 pharmaceutical products including Venofer® (iron sucrose injection, USP), the # 1 selling IV iron therapy in the U.S., which are distributed through its human health subsidiary, American Regent, Inc. Luitpold Pharmaceuticals, also markets dental bone regeneration products and veterinary pharmaceuticals through its Osteohealth and Animal Health divisions respectively. For more information on Luitpold or any of its divisions, please visit: [www.luitpold.com](http://www.luitpold.com)

### **About Daiichi Sankyo**

The Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address the diversified, unmet medical needs of patients in both mature and emerging markets. While maintaining its portfolio of marketed pharmaceuticals for hypertension, hyperlipidemia, and bacterial infections, the Group is engaged in the development of treatments for thrombotic disorders and focused on the discovery of novel oncology and cardiovascular-metabolic therapies. Furthermore, the Daiichi Sankyo Group has created a "Hybrid Business Model," which will respond to market and customer diversity and optimize growth opportunities across the value chain. For more information, please visit [www.daiichisankyo.com](http://www.daiichisankyo.com).

Daiichi Sankyo, Inc., headquartered in Parsippany, New Jersey, is a member of the Daiichi Sankyo Group. For more information on Daiichi Sankyo, Inc., please visit [www.dsi.com](http://www.dsi.com).

Source: Luitpold Pharmaceuticals, Inc. and Daiichi Sankyo, Inc.

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