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Contact Information:
Russell LaMontagne
Corinth Group Communications
917.744.7957

Eric Hohenschuh
Regency Therapeutics, Inc.
631-924-4000

National Registry Study Evaluating Utility of SPRIX® (ketorolac tromethamine) Nasal Spray, a Non-Narcotic Alternative for Pain Management after Emergency Department Care, Begins

AMPED study at UPenn and 14 other hospitals will look at the impact of acute pain treatments on patients after discharge from the Emergency Department

Shirley, NY (June 25, 2012) – Regency Therapeutics, a division of Luitpold Pharmaceuticals, Inc., announced today that a national registry has been launched by a group of academic emergency medicine specialists led by Charles Pollack, MA, MD, FAAEM, FACEP, FAHA, Professor and Chairman, Department of Emergency Medicine, Pennsylvania Hospital, University of Pennsylvania Health System. The purpose of the registry is to evaluate patient experience with SPRIX® (ketorolac tromethamine) Nasal Spray, a non-narcotic pain medication, in the management of pain associated with certain medical problems that cause patients to seek medical care in the emergency department. Outcomes will be compared to those of patients who are prescribed oral narcotics for pain relief. The study, called AMPED (Acute Management of Pain from the Emergency Department), will compare the overall impact – efficacy, safety, economics and patient satisfaction – of these different approaches to pain management from a patient's perspective. SPRIX® Nasal Spray, the first and only intranasal non-steroidal anti-inflammatory drug (NSAID), was approved by the U.S. Food and Drug Administration (FDA) in May 2010 for

the short-term management (up to 5 days) of moderate to moderately severe pain that requires analgesia at the opioid level.

"Moderate to moderately severe pain is one of the most common reasons patients seek care in emergency departments, but emergency department clinicians often do not provide adequate treatment of pain because of ingrained prescribing habits and concerns about the appropriate use of narcotic analgesics," said Dr. Pollack. "One of the goals of our study is to understand the overall impact of acute pain and its different treatments on patients after they leave the emergency department, including patient satisfaction, quality of life, and back-to-work/normal activities outcomes."

More than 12 million people in the United States report using opioid or narcotic pain relievers non-medically[i] and, according to the U.S. Centers for Disease Control and Prevention (CDC), these drugs are involved in more overdose deaths than cocaine and heroin combined.[ii] In 2009, the misuse and abuse of prescription painkillers was responsible for more than 397,000 emergency department visits, or 129.4 visits per 100,000 people, nearly twice as many as heroin (~213,000 visits, or 69 visits per 100,000 people).[iii] The active ingredient in SPRIX® (ketorolac tromethamine) Nasal Spray is not a narcotic (does not bind to opioid receptors) and is non-addictive. In clinical trials, patients showed no withdrawal symptoms upon cessation of ketorolac treatment.[iv]

"We are very interested in comparing the response of emergency room patients to SPRIX® vs. narcotics during the management of acute moderate to moderately severe pain. By providing funds to a group of academically oriented emergency medicine physicians to design and carry out this trial, we felt we could obtain high quality information of interest to both of us," said David Bregman, MD, PhD, Medical Director, Luitpold Pharmaceuticals.

The AMPED study will be led by Dr. Pollack and Knox H. Todd, MD, MPH, FACEP, Professor and Chair of the Department of Emergency Medicine, University of Texas MD Anderson Cancer Center. Joining Drs. Pollack and Todd on the registry's steering committee are emergency medicine physicians Deborah Diercks (UC Davis Medical Center, Sacramento, CA), Sharon Mace (Cleveland Clinic Foundation, Cleveland, OH), and Stephen Thomas (University of

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Oklahoma, Tulsa), and pharmacist John Fanikos (Brigham and Women's Hospital, Boston, MA). AMPED will be conducted at fifteen sites around the nation. Approximately 1,000 patients are expected to be enrolled over an eighteen-month period. Patients will receive SPRIX® and/or a narcotic for the management of acute pain at the time of discharge. Patients will be followed for five days to evaluate a variety of outcomes, including pain relief, adverse effects, activity/work patterns, healthcare resource utilization, and quality of life measures. The AMPED study will be funded by Regency Therapeutics, and conducted by Radnor Registry Research (St Davids, PA) at the 15 participating emergency departments. The study opens to enrollment next month.

"We designed this registry to help us understand better what the options are for treating pain after discharge from the emergency department and how the way we treat pain impacts the total patient experience as they re-enter their lives," said Dr. Todd. "The emergency department, unfortunately, can be a gateway for the misuse and abuse of narcotics. As emergency care providers, we need to balance the real need to treat acute pain, but also manage our responsibility to our patients and the community. Hopefully, this study will help provide us a framework for evaluating alternatives to narcotics for treatment of moderate to moderately severe pain."

Please see Important Safety Information following, **including Boxed Warning**. For additional information about SPRIX® (ketorolac tromethamine) Nasal Spray please visit 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.

About Regency Therapeutics
Regency Therapeutics, a division of Luitpold Pharmaceuticals, Inc., markets innovative pharmaceutical products that offer meaningful alternatives to patients and those that care for them. Currently focused on the treatment of acute pain, Regency seeks to provide fiscally and socially responsible solutions to challenging problems facing customers and the health care system. For more information, please visit: www.regencytherapeutics.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.

Source: Luitpold Pharmaceuticals, Inc.

IMPORTANT SAFETY INFORMATION

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

Limitations of Use
SPRIX® (ketorolac tromethamine) Nasal Spray, a nonsteroidal anti-inflammatory drug (NSAID), is indicated for short-term (up to 5 days in adults) management of moderate to moderately severe pain that requires analgesia at the opioid level. Do not exceed a total combined duration of use of SPRIX® and other ketorolac formulations (IM/IV or oral) of 5 days.

SPRIX® is not indicated for use in pediatric patients and it is not indicated for minor or chronic painful conditions.

Gastrointestinal Risk
Ketorolac tromethamine, including SPRIX®, can cause peptic ulcers, gastrointestinal bleeding and/or perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Therefore, SPRIX® is **contraindicated** in patients with active peptic ulcer disease, in patients with recent gastrointestinal bleeding or perforation, and in patients with a history of peptic ulcer disease or gastrointestinal bleeding. Elderly patients are at greater risk for serious gastrointestinal events.

Bleeding Risk
Ketorolac tromethamine inhibits platelet function and is, therefore, **contraindicated** in patients with suspected or confirmed cerebrovascular bleeding, patients with hemorrhagic diathesis, incomplete hemostasis and those at high risk of bleeding.

Cardiovascular Risk
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.

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SPRIX® (ketorolac tromethamine) Nasal Spray is **contraindicated** for treatment of perioperative 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 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 because of the potential adverse effects of prostaglandin-inhibiting drugs on neonates.

SPRIX® should not be used concomitantly with IM/IV or oral ketorolac, aspirin, or other NSAIDs, or with probenecid or pentoxifylline. When ketorolac is administered with aspirin, its protein binding is reduced, although the clearance of free ketorolac is not altered. The clinical significance of this interaction is not known; however, as with other NSAIDs, concomitant administration of SPRIX® and aspirin is not generally recommended because of the potential of increased adverse effects.

Do not use SPRIX® in patients for whom hemostasis is critical.

Clinical studies, as well as postmarketing observations, have shown that ketorolac can reduce the natriuretic effect of furosemide and thiazides in some patients.

Concomitant use of ACE inhibitors and/or angiotensin II receptor antagonists may increase the risk of renal impairment, particularly in volume-depleted patients. NSAIDs may diminish the antihypertensive effect of ACE inhibitors and/or angiotensin II receptor antagonists. Consider this interaction in patients taking SPRIX® concomitantly with ACE inhibitors and/or angiotensin II receptor antagonists.

Ketorolac can cause serious GI adverse events including bleeding, ulceration, and perforation. Elderly patients are at increased risk for serious GI events.

Use SPRIX® with caution in patients with impaired hepatic function or a history of liver disease.

The pharmacologic activity of SPRIX® in reducing inflammation and fever may diminish the utility of these diagnostic signs in detecting infections.

Avoid contact of SPRIX® (ketorolac tromethamine) Nasal Spray with the eyes. If eye contact occurs, wash out the eye with water or saline, and consult a physician if irritation persists for more than an hour.

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

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should be used with caution in patients taking diuretics or ACE inhibitors. Long-term administration of NSAIDs has resulted in renal papillary necrosis and other renal injury such as interstitial nephritis and nephrotic syndrome.

NSAIDs can cause serious dermatologic adverse reactions such as exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, which can be fatal. These serious events may occur without warning. 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).

NSAIDs can lead to onset of new hypertension or worsening of preexisting hypertension, either of which may contribute to the increased incidence of cardiovascular events. Patients taking thiazides or loop diuretics may have impaired response to these therapies when taking NSAIDs. Fluid retention, edema, retention of NaCl, oliguria, and elevations of serum urea nitrogen and creatinine have been reported in clinical trials with ketorolac. Only use SPRIX® very cautiously in patients with cardiac decompensation or similar conditions.

The most common adverse reactions (incidence ≥ 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 see complete Prescribing Information, including Boxed Warning at www.SPRIX.com.

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[i] U.S. Centers for Disease Control and Prevention (CDC). "Prescription Painkiller Overdoses in the U.S." Accessed 5/15/12. Available at: http://www.cdc.gov/Features/VitalSigns/PainkillerOverdoses/

[ii] CDC. Vital Signs: Overdoses of Prescription Opioid Pain Relievers --- United States, 1999-2008. *Morbidity and Mortality Weekly Report (MMWR)*. November 4, 2011; 60(43):1487-1492. Accessed 5/15/12. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm

[iii] U.S. Substance Abuse & Mental Health Services Administration (SAMHSA). Highlights of the 2009 Drug Abuse Warning Network (DAWN) Findings on Drug-Related Emergency Department Visits. *The DAWN Report*. December 28, 2010. Accessed 5/15/12. Available at: http://www.oas.samhsa.gov/2k10/DAWN034/EDHighlightsHTML.pdf

[iv] SPRIX® [package insert]. Shirley, NY: American Regent, Inc; 2011.

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