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Luitpold Pharmaceuticals, Inc. Receives Complete Response Letter for Injectafer® from the U.S. Food and Drug Administration

Shirley, NY (July 26, 2012) – Luitpold Pharmaceuticals, Inc. had submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Injectafer® (ferric carboxymaltose injection) for the treatment of iron deficiency anemia on September 30, 2011.

As part of this submission, Luitpold Pharmaceuticals provided the FDA with safety and efficacy data from two large scale, multi-center, randomized clinical trials. One trial compared Injectafer® to Venofer® (iron sucrose injection, USP) in patients with iron deficiency anemia and chronic kidney disease. The second study compared Injectafer® to either oral or IV iron (standard of care therapy) in patients with iron deficiency anemia of various etiologies.

In the Complete Response Letter the FDA noted its decision to withhold approval at this time. The decision was not related to any issues with the Injectafer NDA filing, but with Luitpold's manufacturing facility in Shirley, N.Y.

During a recent inspection, issues in the manufacturing facility were noted by FDA inspectors. This is the same facility that is to be used to manufacture Injectafer for the U.S. market.

Luitpold Pharmaceuticals is working with the FDA to resolve the issues found in the FDA's recent inspection.

Luitpold believes it has adequately responded to all the clinical questions concerning Injectafer® raised by the FDA during the current review period.

Injectafer®, a novel IV iron replacement therapy was approved by the UK Medicines & Healthcare products Regulatory Agency (MHRA), in 2007 and acting as a Reference country, supported the subsequent approval of Ferinject® (brand name outside of U.S.) throughout the European Union and the Swiss regulatory agency Swissmedic. Ferinject® is currently registered for use in 40 countries worldwide.

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. Sprix® (ketorolac tromethamine) Nasal Spray is marketed through its Regency Therapeutics Division. For more information on Luitpold or any of its divisions and products, please visit: 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.

Source: Luitpold Pharmaceuticals, Inc. (Shirley, NY)