

For Immediate Release

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**Luitpold Pharmaceuticals, Inc. Resubmits Injectafer[®] NDA to the U. S. Food and Drug
Administration**

The attached is the press release issued on October 13, 2011 (US Time) by Luitpold Pharmaceuticals, Inc., an US affiliate of DAIICHI SANKYO COMPANY LIMITED.



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***Luitpold Pharmaceuticals, Inc. Submits
Injectafer® NDA to the U.S. Food and Drug
Administration***

Shirley, NY (October 13, 2011) – Luitpold Pharmaceuticals, Inc. has submitted a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for Injectafer® (ferric carboxymaltose injection) for the treatment of iron deficiency anemia. The NDA includes data and information from two new large randomized controlled clinical trials investigating the cardiovascular risk profile of high dose Injectafer®. Injectafer® will be marketed in the U.S. by American Regent, Inc., the current distributor of Venofer® (iron sucrose injection, USP), the #1 prescribed IV iron in the U.S.

The submission reflects the conclusion of a clinical study program designed to assess the risk profile of Injectafer® following FDA's issuance of a non-approvable letter in March, 2008 with respect to the original NDA submission.

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

Luitpold Pharmaceuticals looks forward to working closely with the FDA to address any further questions or issues they may have in connection with the NDA.

Injectafer®, the 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 35 countries worldwide.

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

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.