For Immediate Release

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Announce on NDA Submission for Injectafer®

The attached is the press release of Luitpold Pharmaceuticals, Inc., US affiliates of DAIICHI SANKYO COMPANY, LIMITED.

PRESS RELEASE

FOR IMMEDIATE RELEASE
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Luitpold Pharmaceuticals, Inc., Announces NDA Submission for Injectafer® (Ferric Carboxymaltose Injection), a Next Generation Intravenous Iron Product

Shirley, NY - Luitpold Pharmaceuticals, Inc. announced today it has submitted a New Drug Application (NDA) to the U.S Food and Drug Administration (FDA) for a new intravenous iron replacement product, Injectafer® (ferric carboxymaltose injection) (Internal name VIT-45), requesting approval of the product in the treatment of iron deficiency anemia in **heavy uterine bleeding, postpartum, inflammatory bowel disease** and **hemodialysis patients.** The NDA is currently under review. If FDA approval is obtained during the current review period, launch of the product is expected later this year.

Iron deficiency anemia represents a significant health issue in women. Six million women of reproductive age in the U.S. are iron deficient and 3 million have been diagnosed with iron deficiency anemia. More than half of the 4 million women who give birth each year develop iron deficiency and approximately 1 million of these progress to iron deficiency anemia.

Iron deficiency anemia secondary to heavy uterine bleeding or the postpartum state represents a silent epidemic with quality of life deficits comparable to chronic illnesses such as congestive heart failure or chronic kidney disease. These conditions represent a clear unmet medical need due to issues with the current treatment options. The efficacy of oral iron (the most common treatment) is limited by non-compliance due to poor tolerability (from constipation, nausea, etc)

and the inconvenience of long term three time a day dosing. Currently, the only intravenous iron product approved for non-chronic kidney disease-related iron deficiency anemia in the US is iron dextran injection, which carries the risk of life threatening anaphylaxis and has an approved maximum dose of only 100 mg.

Ferric carboxymaltose injection has been studied in patients with heavy uterine bleeding and in postpartum state in clinical trials compared to oral iron three times a day over a period of 6 weeks. Clinical trials in patients with inflammatory bowel disease over 12 weeks also used a comparison to oral iron, while studies in patients on hemodialysis used another currently approved IV iron product as a comparison. In these clinical studies, the product was administered at dosing from 200mg IV push to 1000mg over 15 minutes, an advantage over other currently marketed intravenous iron products. Results of the clinical trials have been favorable and supported the submission of the NDA.

If approved by the FDA, Injectafer (ferric carboxymaltose injection) will be marketed in the U.S. by American Regent, Inc., a subsidiary of Luitpold Pharmaceuticals.

Mary Jane Helenek, President and CEO of Luitpold Pharmaceuticals stated that "We are hopeful that the introduction of ferric carboxymaltose will help raise the awareness of iron deficiency anemia, especially in women of reproductive age, and will provide a safe and effective alternative to oral iron or iron dextran in this population."

Results from the heavy uterine bleeding study were presented last week at the American College of Obstetricians and Gynecologists (ACOG) Annual Clinical Meeting in San Diego. Luitpold Pharmaceuticals will present the data from trials in other indications in the near future.

For more information on anemia in women, please visit www.anemiainwomen.com.

About Luitpold Pharmaceuticals, Inc.

Luitpold Pharmaceuticals, Inc., headquartered in Shirley, NY, manufactures and distributes over 65 pharmaceutical products including Venofer® (iron

sucrose injection, USP) , the leading 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 Co., Ltd. is a major Japanese pharmaceutical company. Injectafer® will be marketed under license from Vifor (International), a company of the Galenica Group. See www.luitpold.com

Source: Luitpold Pharmaceuticals, Inc.

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