LUITPOLD

PRESS RELEASE

FOR IMMEDIATE RELEASE
December 15, 2011

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FDA Assigns PDUFA Date for Injectafer® (ferric carboxymaltose injection) NDA

Shirley, NY - In September, 2011, Luitpold Pharmaceuticals, Inc. submitted a New Drug Application (NDA) with the US Food and Drug Administration (FDA) for ferric carboxymaltose injection for the treatment of iron deficiency anemia. Luitpold today announces that the FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date of August 3, 2012.

The PDUFA action date is a target date for the FDA to complete its review of the New Drug Application (NDA) for Injectafer® (ferric carboxymaltose injection) for the treatment of iron deficiency anemia. The FDA could respond sooner or extend the action date as the review and discussions progress.

If ferric carboxymaltose injection is approved by FDA, it will be marketed in the U.S. by American Regent, Inc. under the name Injectafer®, licensed from Vifor Pharma, a company of the Galenica Group.

Iron Deficiency Anemia (IDA) is a state in which iron stores are inadequate for normal blood formation, as the iron requirements exceed the supply. In severe cases, red cells in a patient with IDA are both microcytic (small) and hypochromic (pale), and values for mean corpuscular volume (MCV) and mean corpuscular Hb concentration (MCHC) are characteristically reduced. According to the World Health Organization (WHO), it is estimated that about 700 million people have iron deficiency anemia (IDA). [Source: World Health Organization. Preventing and controlling Iron Deficiency Anaemia through primary health care].

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)