

For Immediate Release
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**Luitpold Pharmaceuticals, Inc., Comment on FDA Advisory Committee Meeting
To Evaluate Injectafer™ (Ferric Carboxymaltose Injection)**

The attached is the press release issued on February 4, 2008 (US Time) by Luitpold Pharmaceuticals, Inc., US affiliate of DAIICHI SANKYO COMPANY LIMITED.



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PRESS RELEASE

FOR IMMEDIATE RELEASE

February 4, 2008

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FDA Advisory Committee Supports Favorable Risk-Benefit Profile for Injectafer™ (Ferric Carboxymaltose Injection) Under Certain Indications for Use

Shirley, NY - Luitpold Pharmaceuticals, Inc. announced today that on Friday the Drug Safety and Risk Management Advisory Committee of the U.S. Food and Drug Administration (FDA) voted that the available safety and efficacy data support a favorable risk / benefit profile of **Injectafer™** (ferric carboxymaltose injection) (Internal name VIT-45) for the treatment of iron deficiency anemia patients with heavy uterine (HUB) or postpartum bleeding who have an unsatisfactory response to oral iron or are intolerant to oral iron.

“Although the Advisory Committee didn’t support our proposed indication for Injectafer™ – which did not reference the use of oral iron - we are pleased with their recommendations in favor of the more restricted indication,” said Mary Jane Helenek, President & CEO. “Their recommendation establishes a path forward with the FDA. We are committed to working closely with the FDA to see the product through approval.”

The FDA is expected to make a decision on the NDA, requesting approval for the use of Injectafer™ in these patient populations by mid-March, 2008. The agency is not bound by the Committee’s recommendation but takes its advice into consideration when reviewing products for approval.

The development program for Injectafer™ represents the largest prospectively enrolled program of any intravenous iron product ever submitted to the Agency for approval. Data were derived from 12 multi-center trials involving more than 3,000 subjects.

Iron deficiency anemia represents a significant health issue in women. More than half of the 4 million women who give birth each year develop iron deficiency and approximately 1 million of these women progress to iron deficiency anemia. In addition, as many as one in five women will suffer from heavy uterine bleeding, defined as excessive or prolonged blood loss.



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Injectafer™ was approved in 18 countries in Europe in September 2007 and in Switzerland in November 2007.

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) Inc., a company of the Galenica Group. See www.luitpold.com

Source: Luitpold Pharmaceuticals, Inc.

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