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FOR IMMEDIATE RELEASE

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American Regent announces new PDUFA action date for Injectafer® (ferric carboxymaltose injection) NDA for the treatment of iron deficiency anemia

Shirley, NY – (April 8, 2013): American Regent, Inc. announced today that its parent company, Luitpold Pharmaceuticals, Inc., received confirmation that their response to the Injectafer® (ferric carboxymaltose injection) Complete Response Letter issued by the US Food and Drug Administration has been accepted and is currently under review for the treatment of iron deficiency anemia in CKD and non-CKD patients.

The FDA has informed Luitpold that the filing of their response will be subject to a six month Class II review with a PDUFA target action date of July 30, 2013. This acceptance follows the receipt in July 2012, of a Complete Response Letter from the FDA in which the agency noted its decision to withhold approval of Injectafer® until issues it had identified at Luitpold's Shirley NY manufacturing facility were resolved. In the Complete Response Letter, the FDA did not reference any deficiencies related to the safety or efficacy data previously filed for Injectafer®. Accordingly, no additional clinical trial data or further analysis of the previous clinical data was provided.

Injectafer® is manufactured and marketed under the name of Ferinject® by Vifor Pharma (Switzerland) outside of North America. Ferinject is currently registered in 45 countries worldwide.

For more information on American Regent, Inc. or any of its products, please visit:
www.americanregent.com

About American Regent

American Regent, Inc., a wholly owned subsidiary of Luitpold Pharmaceuticals, Inc (a Daiichi Sankyo Group Company), headquartered in Shirley, NY, US, distributes over 80 pharmaceutical products , including Venofer® (iron sucrose injection, USP), the #1 selling IV Iron therapy in the U.S. since 2003.

About Daiichi Sankyo

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 optimise growth opportunities across the value chain. For more information, please visit: www.daiichisankyo.com.

Source: American Regent, Inc.