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PRESS RELEASE

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Venofer® (iron sucrose injection, USP) receives FDA approval for the Treatment of Iron Deficiency Anemia in Pre-Dialysis Patients

Shirley, N.Y. - June 17, 2005: American Regent/Luitpold Pharmaceuticals announced today that the U.S. Food and Drug Administration (FDA) has approved Venofer® (iron sucrose injection, USP) for the treatment of iron deficiency anemia in Chronic Kidney Disease Patients Not on Dialysis.

According to the National Kidney Foundation, 20 million Americans have Chronic Kidney Disease (CKD). Of these, approximately 8 million are considered to be Stages III and IV and many may require intravenous iron supplementation to treat iron deficiency anemia, a common complication of CKD. Patients with kidney failure suffer from a reduced ability to produce erythropoietin leading to impairment of new red blood cell production and eventually iron deficiency anemia. Iron is essential to effective hemoglobin and red blood cell production. Untreated depletion of iron stores leads to iron-deficient erythropoiesis and iron-deficiency anemia.

First approved in 2000 for the treatment of iron deficiency anemia in patients undergoing hemodialysis on supplemental erythropoietin therapy, Venofer® received a positive national coverage decision by CMS in 2001 and has been assigned a specific HCPCS Code: J-1756 for that indication. Venofer®, currently the #1 prescribed IV iron, is the first and only non-dextran IV iron approved for use in the pre-dialysis population. Venofer® is now FDA approved at a higher dose of iron per single dose administration than any other IV iron.

In non-dialysis dependent CKD patients, Venofer® is administered to a total cumulative dose of 1000mg over a 14 day period as a 200mg slow IV injection undiluted over 2 to 5 minutes on 5 different occasions within the 14 day period. There is limited experience, however, with an infusion of 500mg, diluted in 250mL of 0.9% Sodium Chloride over 3.5 to 4 hours on days 1 & 14; hypotension occurred in 2 of the 30 patients administered that dose in the clinical trial.

To learn more about the use of Venofer® in CKD or to obtain a copy of the full prescribing information, please contact American Regent, Inc. at 800-645-1706.

Venofer® is manufactured under license from Vifor (International) Inc., Switzerland

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