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Injectafer® (ferric carboxymaltose injection) receives US FDA approval for the treatment of Iron Deficiency Anemia

Shirley, NY (July 25, 2013) - American Regent Inc., a subsidiary of Luitpold Pharmaceuticals Inc., is pleased to announce that Injectafer® (ferric carboxymaltose injection) has received U.S. Food and Drug Administration (FDA) approval. Injectafer® is a parenteral iron replacement product used for the treatment of iron deficiency anemia (IDA) in adult patients who have intolerance to oral iron or have had an unsatisfactory response to oral iron. Injectafer® is also indicated for iron deficiency anemia in adult patients with non-dialysis dependent chronic kidney disease (NDD-CKD).

“We are pleased with the FDA’s approval of Injectafer® as the first high dose non-dextran IV iron indicated to treat adult patients with iron deficiency anemia in a broad patient population. Iron deficiency anemia is a serious health condition which results in a diminished quality of life for those patients it afflicts. Current therapies are either limited to treating IDA in chronic kidney disease patients and/or require infusions over several hours or significant multiple dosing sessions. Now, with Injectafer®, physicians can effectively and efficiently treat these patients with a single dose of up to 750 mg of iron via an IV push injection or over a 15 minute infusion followed by a second dose 7 days later for a total treatment of up to 1500 mg of iron. This is a very important treatment advance for the correction of iron deficiency anemia and we are very excited to be able to provide this new innovation to US physicians,” commented Mary Jane Helenek, R.Ph. M.S., M.B.A., President and CEO of American Regent Inc.

About Iron Deficiency Anemia

In the U.S. there are an estimated 7.5 million people with IDA, a condition that occurs when body iron stores are inadequate for normal red blood cell production. IDA is a frequent complication in many GI disease states and conditions, affecting up to one-third of inflammatory bowel disease patients and up to 24% of patients who have undergone gastric bypass surgery. It is also prevalent in children and women, with over 3 million U.S. women of childbearing age affected due to conditions such as heavy uterine bleeding, postpartum anemia, and pregnancy.

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About Injectafer®

Injectafer® (ferric carboxymaltose injection) is the first non-dextran IV iron approved for the treatment of adult patients with IDA of various etiologies in addition to use in non-dialysis dependent CKD patients. A single dose of up to 750 mg of Injectafer® can be administered undiluted as an IV push injection at a rate of 100 mg/minute or as an IV infusion in up to 250 mL 0.9 % Sodium Chloride Injection, USP, over at least 15 minutes.

The safety and efficacy of Injectafer® for treatment of iron deficiency anemia were evaluated in two clinical trials (Trial 1 and Trial 2) in which Injectafer® was administered at a dose of 15 mg/kg body weight up to a maximum single dose of 750 mg of iron on two occasions separated by at least 7 days up to a maximum cumulative dose of 1500 mg of iron. The inclusion / exclusion criteria for both studies allowed patients with various comorbidities, characteristic of this broad patient population. Additionally, patients with a history of drug allergies were included in the trials, providing robust safety data in this difficult to treat subset of patients.

Trial 1 compared two 750 mg doses of Injectafer® to either oral or IV iron (standard of care therapy) in patients with iron deficiency anemia of various etiologies and included approximately 1000 patients half of whom received Injectafer®. In this trial, Injectafer® raised hemoglobin more than oral iron or IV standard of care therapy, with a mean change in hemoglobin of 1.57 g/dL vs 0.80 g/dL when compared to oral iron and 2.90 g/dL vs 2.16 g/dL when compared with IV standard of care therapy. These increases were statistically significant ($p=0.001$). Further, cardiovascular safety was evaluated based on an adjudicated composite safety endpoint comprised of death, myocardial infarction, stroke, unstable angina, congestive heart failure, arrhythmias, hypertension and hypotension. Rates of the composite safety endpoint were 3.95% for Injectafer® vs 4.90% when compared to IV standard of care and at 2.85% for Injectafer® vs 1.58% when compared to oral iron.

Trial 2, the largest head-to-head study of IV iron in high risk patients with iron deficiency anemia and CKD, compared Injectafer® to Venofer® (iron sucrose injection, USP) and included 2561 patients, approximately half of whom received Injectafer®. In these high risk patients, two 750 mg doses of Injectafer® raised hemoglobin more than five 200 mg doses of Venofer®, with a change in hemoglobin of 1.13 g/dL for Injectafer® vs 0.92 for Venofer®. These increases were statistically significant (treatment difference [95% CI] = 0.21 [0.13, 0.28]). Rates of the adjudicated composite safety endpoint comprised of death, myocardial infarction, stroke, unstable angina, congestive heart failure, arrhythmias, hypertension and hypotension were statistically similar at 13.71% for Injectafer® vs 12.14% for Venofer® (treatment difference [95% CI] = 1.57% [-1.10%, 4.25%]). Rates of a composite of death, myocardial infarction and stroke were 1.88% for Injectafer® vs 2.72% for Venofer®.

The entire Injectafer® program consisted of over 11,071 patients treated with the study product or a comparator. This represents the largest safety database ever submitted to the FDA to support the approval of an IV iron product.

Injectafer® is manufactured and marketed under the name of Ferinject® (Ferric Carboxymaltose) by Vifor Pharma (Switzerland) outside of North America. Ferinject® is currently registered in 46 countries and is marketed in 37 countries worldwide.

About American Regent

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

About Vifor Pharma

Vifor Pharma, a company of the Galenica Group, is a world leader in the discovery, development, manufacturing and marketing of pharmaceutical products for the treatment of iron deficiency. The company also offers a diversified portfolio of prescription medicines as well as over-the-counter (OTC) products. Vifor Pharma, headquartered in Zurich, Switzerland, has an increasingly global presence and a broad network of affiliates and partners around the world. For more information about Vifor Pharma and its parent company Galenica, please visit www.viforpharma.com and www.galenica.com.

Venofer® and Injectafer® are manufactured under license from, and are registered trademarks of, Vifor (International) Inc., Switzerland.

Source: Luitpold Pharmaceuticals, Inc. (Shirley, NY)

IMPORTANT SAFETY INFORMATION

Injectafer® (ferric carboxymaltose injection) is an iron replacement product indicated for the treatment of iron deficiency anemia in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron, and in adult patients with non-dialysis dependent chronic kidney disease. Injectafer® is contraindicated in patients with hypersensitivity to Injectafer® or any of its inactive components

Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and fatal, have been reported in patients receiving Injectafer®. Patients may present with shock, clinically significant hypotension, loss of consciousness, and/or collapse. Monitor patients for signs and symptoms of hypersensitivity during and after Injectafer® administration for at least 30 minutes and until clinically stable following completion of the infusion. Only administer Injectafer® when personnel and therapies are immediately available for the treatment of serious hypersensitivity reactions. In clinical trials, serious, anaphylactic/anaphylactoid reactions were reported in 0.1% (2/1775) of subjects receiving Injectafer®. Other serious or severe adverse reactions potentially associated with hypersensitivity which included, but were not limited to, pruritus, rash, urticaria, wheezing, or hypotension were reported in 1.5% (26/1775) of these subjects.

In clinical studies, hypertension was reported in 3.8% (67/1775) of subjects. Transient elevations in systolic blood pressure, sometimes occurring with facial flushing, dizziness, or nausea were observed in 6% (106/1775) of subjects. These elevations generally occurred immediately after dosing and resolved within 30 minutes. Monitor patients for signs and symptoms of hypertension following each Injectafer® administration.

In two randomized clinical studies, a total of 1775 patients were exposed to Injectafer®, 15/mg/kg of body weight, up to a single maximum dose of 750 mg of iron on two occasions, separated by at least 7 days, up to a cumulative dose of 1500 mg of iron. Adverse reactions reported by ≥ 2% of Injectafer® treated patients were nausea (7.2%); hypertension (3.8%); flushing/hot flush (3.6%); blood phosphorus decrease (2.1%); and dizziness (2.0%).

The following serious adverse reactions have been most commonly reported from the post-marketing spontaneous reports: urticaria, dyspnea, pruritus, tachycardia, erythema, pyrexia, chest discomfort, chills, angioedema, back pain, arthralgia and syncope.