



**FOR IMMEDIATE RELEASE**

**Contact:**

Eleanor Halgren  
Corinth Group  
978-879-9244

**American Regent's Injectafer<sup>®</sup> (Ferric Carboxymaltose Injection) Assigned Q Code by Centers for Medicare and Medicaid Services**

*Product-specific code for iron deficiency anemia drug will streamline provider billing and reimbursement*

**Shirley, NY (May 1, 2014) - American Regent, Inc.**, a subsidiary of Luitpold Pharmaceuticals, Inc. (a Daiichi Sankyo Group Company), announced today that the Centers for Medicare & Medicaid Services (CMS) has granted a unique product reimbursement code, or Q code, for Injectafer<sup>®</sup> (ferric carboxymaltose injection), the first and only high-dose non-dextran intravenous iron for iron deficiency anemia (IDA) of various etiologies. Injectafer<sup>®</sup> was approved by the U.S. Food and Drug Administration (FDA) on July 25, 2013 for the treatment of IDA in adult patients who have intolerance to oral iron or who have had an unsatisfactory response to oral iron, or in adult patients who have non-dialysis dependent chronic kidney disease. The new Q code, Q9970, will become effective on July 1, 2014. Reimbursement to providers can be delayed with a non-specific product code, which is used for all new injectable products until CMS assigns a unique Q code. The Injectafer<sup>®</sup>-specific billing code will help streamline the billing and reimbursement process for healthcare providers who use Injectafer<sup>®</sup> in patient care.

“We are very pleased with the level of interest in Injectafer<sup>®</sup> from providers among multiple specialties, and it is important that they receive timely reimbursement,” said Jackie Beltrani, Vice President, Commercial Operations, American Regent. “The designation of this Q code for Injectafer<sup>®</sup> will help simplify the billing process and hasten reimbursement to providers who are treating adult patients with iron deficiency anemia using this new high-dose intravenous iron.”

“The CMS assignment of Q code for Injectafer<sup>®</sup> is one more significant step towards making Injectafer<sup>®</sup> available to all healthcare providers who treat iron deficiency anemia,” added Ms. Beltrani.

Injectafer<sup>®</sup> can be administered as a single dose of up to 750 mg by IV push injection over 7.5 minutes or 15-minute infusion, and can be followed by a second dose 7 days later for a total cumulative dose of up to 1500 mg of iron per treatment course. The majority of patients (93 to 95 percent) in trials of Injectafer<sup>®</sup> received the target dose of 1500 mg. The full prescribing information for Injectafer<sup>®</sup> (ferric carboxymaltose injection) is available at:

[http://www.injectafer.com/files/Prescribing\\_Information.pdf](http://www.injectafer.com/files/Prescribing_Information.pdf).

### **About Iron Deficiency Anemia**

There are over 7.5 million people in the US with iron deficiency anemia (IDA), a condition that occurs when body iron stores are inadequate for normal red blood cell production. Fatigue, difficulty concentrating, shortness of breath, and dizziness are common symptoms, significantly impacting patients' quality of life. IDA is a common complication of many diseases and conditions, including cancer, chronic kidney disease, gastrointestinal conditions, obstetric and gynecological conditions and congestive heart failure. It affects up to one-third of inflammatory bowel disease patients and nearly one-quarter of patients who have undergone gastric bypass surgery. IDA is prevalent in women, affecting over 3 million US women of childbearing age due to conditions such as heavy uterine bleeding, postpartum anemia, and pregnancy. Blood disease expert Lawrence Goodnough, MD, from Stanford University Medical Center and Lynell D'Sylva, RN, BSN, from American Regent recently discussed the importance of maintaining sufficient iron levels on Lifetime's special, *The Balancing Act*. The full segment can be viewed [here](#).

### **About Injectafer®**

Injectafer® (ferric carboxymaltose injection) is the first non-dextran intravenous (IV) iron approved for the treatment of adult patients with iron deficiency anemia of various etiologies who are intolerant to or who have had an unsatisfactory response to oral iron, in addition to use in adult non-dialysis dependent chronic kidney disease (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. Injectafer® is reimbursable using Q code 9970 for product-specific reimbursement, C code C9441 (Medicare-only hospital outpatient settings), and J code J3490 (delivery in physician offices and non-Medicare outpatient settings). The full prescribing information for Injectafer® is available at: [http://www.injectafer.com/files/Prescribing\\_Information.pdf](http://www.injectafer.com/files/Prescribing_Information.pdf).

The safety and efficacy of Injectafer® for treatment of iron deficiency anemia was 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). In addition, a significantly higher proportion of patients who received Injectafer® achieved a hemoglobin of >12 g/dL during the course of treatment compared to both oral iron (57.0% vs. 29.1%, respectively) and IV standard of care (50.6% vs. 24.5%, respectively) (p=0.001 for both). 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<sup>®</sup> (ferric carboxymaltose injection) vs. 4.90% when compared to IV standard of care and 2.85% for Injectafer<sup>®</sup> 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<sup>®</sup> to Venofer<sup>®</sup> (iron sucrose injection, USP; American Regent, Inc., Shirley, NY) and included 2561 patients, approximately half of whom received Injectafer<sup>®</sup>. In these high-risk patients, two 750-mg doses of Injectafer<sup>®</sup> increased hemoglobin more than five 200-mg doses of Venofer<sup>®</sup>, with a change in hemoglobin of 1.13 g/dL for Injectafer<sup>®</sup> vs. 0.92 for Venofer<sup>®</sup>. These increases were statistically significant (treatment difference [95% CI] = 0.21 [0.13 to 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<sup>®</sup> vs. 12.14% for Venofer<sup>®</sup> (treatment difference [95% CI] = 1.57% [- 1.10% to 4.25%]). Rates of a composite of death, myocardial infarction and stroke were 1.88% for Injectafer<sup>®</sup> vs. 2.72% for Venofer<sup>®</sup>.

Injectafer<sup>®</sup> is manufactured and marketed under the name of Ferinject<sup>®</sup> (ferric carboxymaltose injection) by Vifor Pharma (Switzerland) outside of North America.

## **IMPORTANT SAFETY INFORMATION**

### **INDICATIONS/CONTRAINDICATIONS**

Injectafer<sup>®</sup> (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<sup>®</sup> is contraindicated in patients with hypersensitivity to Injectafer<sup>®</sup> or any of its inactive components.

### **WARNINGS AND PRECAUTIONS**

**Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and fatal, have been reported in patients receiving Injectafer<sup>®</sup>. 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<sup>®</sup> administration for at least 30 minutes and until clinically stable following completion of the infusion. Only administer Injectafer<sup>®</sup> 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<sup>®</sup>. 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<sup>®</sup> (ferric carboxymaltose injection) administration. In the 24 hours following administration of Injectafer<sup>®</sup>, laboratory assays may overestimate serum iron and transferrin bound iron by also measuring the iron in Injectafer<sup>®</sup>.

### **ADVERSE REACTIONS**

In two randomized clinical studies, a total of 1775 patients were exposed to Injectafer<sup>®</sup>, 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  $\geq 2\%$  of Injectafer<sup>®</sup>-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.

**See full prescribing information at [www.injectafer.com](http://www.injectafer.com).**

### **About American Regent**

American Regent Inc., a wholly owned subsidiary of Luitpold Pharmaceuticals, Inc. (a Daiichi Sankyo Group Company), headquartered in Shirley, NY, distributes over 80 pharmaceutical products, including Venofer<sup>®</sup> (iron sucrose injection, USP), the #1 selling intravenous Iron therapy in the United States, and Injectafer<sup>®</sup> (ferric carboxymaltose injection), the first and only high-dose intravenous iron for iron deficiency anemia of various etiologies in adult patients intolerant to oral iron or who have had an unsatisfactory response to oral iron, in addition to use in adult non-dialysis dependent chronic kidney disease patients. For more information, please visit [www.americanregent.com](http://www.americanregent.com).

### **About Luitpold Pharmaceuticals, Inc.**

Luitpold Pharmaceuticals, Inc., a Daiichi Sankyo Group Company headquartered in Shirley, NY, manufactures over 80 pharmaceutical products, including Venofer<sup>®</sup> (iron sucrose injection, USP), the # 1 selling intravenous iron therapy in the US, and Injectafer<sup>®</sup> (ferric carboxymaltose injection), the first and only high-dose intravenous iron for iron deficiency anemia of various etiologies in adult patients intolerant to oral iron or who have had an unsatisfactory response to oral iron, in addition to use in adult non-dialysis dependent chronic kidney disease patients, 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. For more information on Luitpold or any of its divisions, please visit: [www.luitpold.com](http://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](http://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](http://www.viforpharma.com) and [www.galenica.com](http://www.galenica.com).

Venofer<sup>®</sup> (iron sucrose injection, USP) and Injectafer<sup>®</sup> (ferric carboxymaltose injection) are manufactured under license from and are registered trademarks of Vifor (International) Inc., Switzerland.

Source: American Regent, Inc. (Shirley, NY)