Press Release

American Regent Announces Enrollment of First Patient in Phase 3 Trial to Investigate Injectafer® (Ferric Carboxymaltose) as Treatment for Heart Failure with Iron Deficiency

- HEART-FID is one of the largest studies to look at intravenous (IV) ferric carboxymaltose (FCM) iron therapy as a treatment for heart failure in patients with iron deficiency
- HEART-FID is anticipated to enroll more than 3,000 adult patients across North America

Shirley, NY (April, 24, 2017) – American Regent, a member of the Daiichi Sankyo Group, announced that the first patient has been enrolled into the phase 3 clinical trial, HEART-FID. This double-blind, multicenter, prospective, randomized, placebo-controlled study will assess the efficacy and safety of iron therapy using intravenous (IV) ferric carboxymaltose (FCM), relative to placebo, in the treatment of patients with heart failure, iron deficiency and a reduced ejection fraction.[1]

"Iron deficiency affects up to half of all heart failure patients and is associated with impaired exercise tolerance, and mortality in patients with or without anemia,[2]" said Adrian F. Hernandez, MD, MHS, Duke Clinical Research Institute and HEART-FID study chair. "HEART-FID has the potential to provide a deeper understanding of how intravenous iron may help patients with heart failure with a low ejection fraction."

Heart failure prevalence has increased from 5.7 million (2009 to 2012) to 6.5 million (2011 to 2014) in Americans ≥20 years of age.[3] About half of people who develop heart failure die within five years of diagnosis.[4]

HEART-FID will assess the effects of IV FCM compared to placebo on the following outcome measures: the 12-month rate of death, hospitalization for worsening heart failure, and the six-month change in six-minute walk test (6MWT) for patients in heart failure with iron deficiency.[1] The study is anticipated to enroll more than 3,000 adult patients across North America.[1]

"We are pleased to enroll our first patient in the HEART-FID trial, one of the largest studies looking at this specific condition, and we look forward to further recruitment," said Sumita Chowdhury, MD, MPH, FACC, MBA, Head of Clinical Research & Development, American Regent. "Heart failure in relation to iron deficiency is an important area of research for American Regent."

Use of Injectafer® as a treatment for heart failure with iron deficiency is investigational and has not been approved by the U.S. Food and Drug Administration (FDA) as such. Additional information about the trial, including eligibility criteria and a list of clinical trial sites can be found at: https://clinicaltrials.gov/ct2/show/NCT03037931.

About the HEART-FID Trial
HEART-FID is a randomized, double-blind, placebo-controlled study in North America to investigate the efficacy and safety of Injectafer® (ferric carboxymaltose) as a treatment for heart failure with iron deficiency. The primary outcome measure includes: a combination of the 12-month rate of death, hospitalization for worsening heart failure, and the six-month change in the six-minute walk test (6MWT) for patients in heart failure with iron deficiency. After an initial screening period of up to 28 days, eligible participants will be stratified by region and randomized in a 1:1 ratio to FCM or placebo for treatment.

About Iron Deficiency and Heart Failure
Approximately ten million people are iron deficient in the United States.[5] Iron deficiency is also a common comorbidity that affects up to 50 percent of heart failure patients.[2] HEART-FID is one of the largest clinical trials to look at iron therapy as a treatment for heart failure in patients with iron deficiency.

About Injectafer®
Injectafer® is an intravenous form of iron used to treat iron deficiency anemia (IDA) in adults who have an intolerance to oral iron or have had an unsatisfactory response to oral iron or have non-dialysis dependent chronic kidney disease.[7] Injectafer® is not approved to treat the symptoms or improve quality of life in patients with IDA.

INDICATIONS
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.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
Injectafer® is contraindicated in patients with hypersensitivity to Injectafer® 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®. 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 the 24 hours following administration of Injectafer®, laboratory assays may overestimate serum iron and transferrin bound iron by also measuring the iron in Injectafer®.

ADVERSE REACTIONS

In two randomized clinical studies, a total of 1,775 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.

About American Regent

American Regent is a leader in the development, manufacturing and sales of generic and branded IV iron medications. With a history of 50 years in generic specialty injectables, American Regent has sales approaching one billion dollars from products manufactured in our facilities in the United States. American Regent strives for continuous improvement to bring to market high quality innovative medications to meet unmet medical needs, and produces high quality accessible generic medications covering a wide array of therapeutic areas. American Regent is a member of the Daiichi Sankyo Group; and is headquartered in Shirley, NY. For more information, please visit www.americanregent.com.

References:

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