

## FDA Approves Feraheme

**FDA Approves Feraheme to Treat Iron Deficiency Anemia in Adult Chronic Kidney Disease Patients** *The U.S. Food and Drug Administration (FDA) has granted marketing approval for Feraheme (ferumoxytol) Injection for intravenous (IV) use as an iron replacement therapy for the treatment of iron deficiency anemia in adult patients with chronic kidney disease. The recommended dose of Feraheme is an initial 510 mg IV injection followed by a second 510 mg IV injection three to eight days later. Feraheme should be administered as an undiluted IV injection delivered at a rate of up to 1 mL/sec (30 mg/sec). The recommended Feraheme dose may be readministered to patients with persistent or recurrent iron deficiency anemia.*

Feraheme is expected to be commercially available in the U.S. during the second half of July 2009. Feraheme will be distributed primarily through wholesalers and specialty distributors. The Company will market and sell Feraheme through its commercial organization consisting of approximately 150 seasoned professionals, including an 80-person specialized sales force, an experienced account management and reimbursement team, and a contract nurse team.

“Feraheme offers patients across the continuum of chronic kidney disease, including patients not on dialysis and patients on dialysis, a new paradigm for the treatment of iron deficiency anemia,” commented Brian J.G. Pereira, MD, President and Chief Executive Officer of AMAG. “We are extremely pleased with the FDA's approval of Feraheme, and we are well prepared and excited to bring this new treatment option to patients and physicians.”

“Iron deficiency anemia is a significant problem in patients with chronic kidney disease and is frequently underdiagnosed and undertreated,<sup>1,2</sup>” said Bryan Becker, MD, President of the National Kidney Foundation. “We welcome the availability of a new therapy option for chronic kidney disease patients affected by iron deficiency anemia.”

## Clinical Data

Feraheme has been proven to be a safe and effective therapy for treating iron deficiency anemia in adult chronic kidney disease patients. The FDA approval of Feraheme was based on safety and efficacy results from four Phase III studies of patients with chronic kidney disease and iron deficiency anemia. These studies consisted of three open-label, multi-center, randomized safety and efficacy clinical studies and a fourth double-blind, multi-center, randomized, placebo-controlled cross-over safety study. Each of the three pivotal safety and efficacy studies achieved statistical significance in its primary endpoint: the mean change in hemoglobin from baseline at Day 35 after the first dose. Feraheme significantly increased hemoglobin levels as compared to oral iron across the spectrum of chronic kidney disease. Overall, 1,726 subjects were exposed to Feraheme in the development program, including 1,562 patients with all stages of chronic kidney disease.

In accordance with the Pediatric Research Equity Act (PREA) requirement, the Company will conduct two post-marketing studies in the pediatric chronic kidney disease population; one in patients on dialysis and the other in patients not on dialysis. Each study will enroll approximately 75 subjects, collecting pharmacokinetic, safety and efficacy data as compared to oral iron. The Company expects to commence these studies in 2010.

**Important Safety Information** Feraheme is indicated for the treatment of iron deficiency anemia in adult patients with chronic kidney disease. Feraheme is contraindicated in patients with evidence of iron overload, known hypersensitivity to Feraheme or any of its components, and patients with anemia not caused by iron deficiency.

In clinical studies, hypotension was reported in 1.9% (33/1,726) of subjects receiving Feraheme, including three patients with serious hypotensive reactions. Adverse reactions potentially associated with hypersensitivity (e.g., pruritus, rash, urticaria or wheezing) were reported in 3.7% (63/1,726) of these subjects including 0.2% (3/1,726) with serious hypersensitivity reactions. Patients should be observed for signs and symptoms of hypersensitivity for at least 30 minutes following Feraheme injection and the drug should only be administered when treatment of hypersensitivity reactions is readily available. Excessive therapy with parenteral iron can lead to excess storage of iron with the possibility of iatrogenic hemosiderosis. Patients should be regularly monitored for hematologic response during parenteral iron therapy, noting that lab assays may overestimate serum iron and transferrin bound iron values in the 24 hours following administration of Feraheme. As a superparamagnetic iron oxide, Feraheme may transiently affect magnetic resonance diagnostic imaging studies for up to 3 months following the last Feraheme dose. Feraheme will not affect X-ray, computed tomography (CT), positron emission tomography (PET), single photon emission computed tomography (SPECT), ultrasound, or nuclear imaging.

In clinical trials, the most commonly occurring adverse reactions in Feraheme treated patients versus oral iron treated patients reported in  $\geq 2\%$  of chronic kidney disease patients were diarrhea (4.0% vs. 8.2%), nausea (3.1% vs. 7.5%), dizziness (2.6% vs. 1.8%), hypotension (2.5% vs. 0.4%), constipation (2.1% vs. 5.7%) and peripheral edema (2.0% vs. 3.2%). In clinical trials, adverse reactions leading to treatment discontinuation and occurring in 2 or more Feraheme-treated patients included hypotension, infusion site swelling, increased serum ferritin level, chest pain, diarrhea, dizziness, ecchymosis, pruritus, chronic renal failure, and urticaria.

*(Sumber : FDA – drugs.com)*