



FOR IMMEDIATE RELEASE

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**FDA Approves Feraheme™ to Treat Iron Deficiency Anemia in
Adult Chronic Kidney Disease Patients**

Product launch expected in the second half of July 2009

LEXINGTON, MA (June 30, 2009) – AMAG Pharmaceuticals, Inc. (NASDAQ:AMAG) today announced that 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,^{1,2}" 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.

Click [here](#) to view *Feraheme*'s product insert which is also available on our website at www.amagpharma.com.

Conference Call and Webcast Access

AMAG Pharmaceuticals, Inc. will host a webcast and conference call tomorrow at 8:30 a.m. ET to discuss today's announcement.

To access the conference call via telephone, please dial (877) 412-6083 from the U.S. or (702) 495-1202 for international callers. A telephone replay will be available from approximately 11:30 a.m. ET on July 1, 2009 through midnight July 3, 2009. To access a replay of the conference call, dial (800) 642-1687 from the U.S. or (706) 645-9291 for international access. The passcode for the live call and the replay is 18122806.

An audio webcast of the call will be available through the Investors section of the Company's website at www.amagpharma.com. A replay of the webcast will also be available from approximately 10:30 a.m. ET on July 1, 2009, through midnight July 31, 2009.

About AMAG Pharmaceuticals, Inc.

AMAG Pharmaceuticals, Inc. is a biopharmaceutical company that utilizes its proprietary technology for the development and commercialization of a therapeutic iron compound to treat iron deficiency anemia and novel imaging agents to aid in the diagnosis of cancer and cardiovascular disease. For additional company and product information please visit www.amagpharma.com.

Feraheme was developed by the Company and is composed of superparamagnetic iron oxide particles with a proprietary semi-synthetic carbohydrate coating.

Feraheme™ is a trademark of AMAG Pharmaceuticals, Inc.

Forward Looking Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Any statements contained herein which do not describe historical facts, including but not limited to, statements regarding our anticipated Feraheme availability and launch timing, and our post marketing pediatric studies and the timing thereof, are forward looking statements which involve risks and uncertainties that could cause actual results to differ materially from those discussed in such forward looking statements. Such risks and uncertainties include: (1) uncertainties regarding our ability to manufacture Feraheme, (2) the fact that we have limited sales and marketing expertise, (3) uncertainties regarding our ability to successfully compete in the intravenous iron replacement market, (4) uncertainties regarding our ability to obtain favorable coverage, pricing and reimbursement for Feraheme, if approved, (5) uncertainties relating to our patents and proprietary rights, and (6) other risks identified in our Securities and Exchange Commission filings, including our Annual Report on Form 10-K for the fiscal year ended December 31, 2008. We caution you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. We disclaim any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

¹ Fishbane S, Pollack S, Feldman HI, Joffe MM. Iron indices in chronic kidney disease in the National Health and Nutritional Examination Survey 1988-2004. Clin J Am Soc Nephrol. 2009 Jan;4(1):57-61.

² Curtis BM, Barrett BJ, Djurdjev O, Singer J, Levin A. Evaluation and treatment of CKD patients before and at their first nephrologist encounter in Canada. Am J Kidney Dis. 2007 Nov;50(5):733-42