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NEW FORM OF INTRAVENOUS IRON TREATS ANEMIA IN CHRONIC KIDNEY DISEASE PATIENTS ON DIALYSIS

*Phase 3 Clinical Trial Highlights Safety and Efficacy Profile of Ferumoxytol
for Patients with this Common Complication*

Washington, DC (Friday, January 23, 2009) — Ferumoxytol, a novel intravenous form of iron that permits rapid administration of large doses, has been shown to be effective for treating iron deficiency in chronic kidney disease (CKD) patients on dialysis, according to a clinical trial appearing in the February 2009 issue of the *Clinical Journal of the American Society Nephrology* (CJASN). The results indicate that this new agent may become an important treatment option for CKD patients.

Because blood is removed during dialysis, CKD patients undergoing this treatment often have anemia, or low red blood cell counts. These patients also are often iron deficient and must receive supplemental iron. While current treatment guidelines recommend intravenous iron for these patients, many clinicians believe that oral iron is much safer than intravenous iron, which has been associated with hypersensitivity reactions and low blood pressure. However, a new form of intravenous iron, ferumoxytol, may be a safe and effective alternative to other forms of iron therapy. Ferumoxytol appears to contain less free iron and be less immunogenic than other intravenous forms of iron.

Robert Provenzano, MD, FASN, of St. John Hospital and Medical Center in Detroit, MI, and his colleagues conducted a phase three clinical trial that compared ferumoxytol with oral iron. The trial enrolled 230 anemic patients with late stage CKD who were on dialysis. Patients received either two injections of 510 mg ferumoxytol within seven days or 200 mg oral iron daily for 21 days. The investigators measured the change in hemoglobin in patients from the start of the trial to day 35.

The two injections of ferumoxytol led to significantly greater hemoglobin increases compared with oral iron supplementation. Specifically, ferumoxytol caused an average of 1.02 g/dL increase in hemoglobin at day 35 compared with 0.46 g/dL with oral iron. Also, twice as many ferumoxytol-treated patients than oral iron-treated patients achieved a ≥ 1 g/dL hemoglobin increase at day 35 (49.0% vs 25.0%). In addition, ferumoxytol was found to be well tolerated relative to oral iron, with 8.2% of ferumoxytol-treated subjects

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and 15.9% of oral iron-treated subjects experiencing adverse reactions considered by the investigator to be related to study treatment.

“Ferumoxytol administered as two rapid intravenous injections of 510 mg each within a week’s time, led to significantly greater hemoglobin increases and was well tolerated as compared with oral iron,” said Dr. Provenzano. He added that the study’s findings also provide insight into factors that affect greater hemoglobin response to intravenous iron treatment, which makes ferumoxytol a potentially attractive treatment option for anemic hemodialysis patients.”

AMAG Pharmaceuticals, Inc. funded the study, and its employees identified study sites, monitored the study to ensure adherence to Good Clinical Practice, and performed data analyses according to the predefined statistical analysis plan. Dr. Provenzano is a member of the Clinical Studies Steering Committee of AMAG Pharmaceuticals, Inc. Authors Brian Pereira, MD and Louis Brenner, MD are employees of AMAG Pharmaceuticals, Inc. Brigitte Schiller, MD and Daniel Coyne, MD were ferumoxytol study investigators. An abstract of some of these findings was submitted to the October 2007 ASN Meeting.

The article, entitled “Ferumoxytol as an Intravenous Iron Replacement Therapy in Hemodialysis Patients,” will appear online at <http://cjasn.asnjournals.org/> on January 28, 2009, and in the February 2009 print issue of CJASN.

ASN is a not-for-profit organization of 11,000 physicians and scientists dedicated to the study of nephrology and committed to providing a forum for the promulgation of information regarding the latest research and clinical findings on kidney diseases. ASN publishes the *Journal of the American Society of Nephrology* (JASN), CJASN, the *Nephrology Self-Assessment Program* (NephSAP), and *ASN Kidney News*.

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