Feraheme® (ferumoxytol) – Expanded indication

- On February 5, 2018, AMAG Pharmaceuticals announced the FDA approval of Feraheme (ferumoxytol) injection for the treatment of iron deficiency anemia (IDA) in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron.
    - Previously, Feraheme was only approved for use in IDA patients who have chronic kidney disease.
- The safety and efficacy of Feraheme's expanded indication is based on data from three clinical studies of 3,410 patients with IDA who were intolerant to oral iron therapy or in whom oral iron could not be used. Patients were randomized to placebo, iron sucrose, or Injectafer® (ferric carboxymaltose).
    - In studies 1 and 2, the primary endpoint was the proportion of patients with a hemoglobin (Hgb) increase of ≥ 2.0 g/dL at any time from baseline to week 5**.**
    - The Feraheme treatment group had a significantly larger proportion of patients achieving the primary endpoint vs. placebo (81.1% vs. 5.5% [95% CI: 71.2, 80.0]; p ≤ 0.001). The Feraheme and iron sucrose treatment groups demonstrated similar proportions of patients achieving the primary endpoint (84% vs. 81.4% [95% CI: -3.9, 9.1]).
    - In addition, a greater proportion of patients achieved Hgb levels ≥ 12 g/dL at any time from baseline to week 5 and a greater mean change in transferrin saturation with Feraheme vs. placebo or iron sucrose.
    - In study 3, the Feraheme group demonstrated non-inferiority to Injectafer with respect to the percentage of patients who experienced moderate-to-severe hypersensitivity reactions (including anaphylaxis) or moderate-to-severe hypotension. Patients treated with Feraheme demonstrated a smaller increase in mean change in Hgb from baseline to week 5 vs. Injectafer (1.38 g/dL vs. 1.63 g/dL [95% CI: -0.35, -0.13]).
- Feraheme carries a boxed warning for risk for serious hypersensitivity/anaphylaxis reactions.
- The recommended dose of Feraheme for both indications is an initial 510 mg dose administered as an intravenous infusion followed by a second 510 mg dose 3 to 8 days later. Refer to the Feraheme drug label for further dosing instructions.