CSN Annual Meeting 2013
April 24-28th, 2013
Montréal, Québec

THE FIRST STUDY (FERUMOXYTOL COMPARED TO IRON SUCROSE TRIAL) – SAFETY AND EFFICACY OF FERUMOXYTOL WITH IRON SUCROSE FOR THE TREATMENT OF IRON DEFICIENCY ANEMIA IN PATIENTS WITH CHRONIC KIDNEY DISEASE (CKD): CANADIAN PARTICIPATION

François Madore[1], Bharat Nathoo[2], Paul Barré[3], Adeera Levin[4], Iain C. Macdougall[5], Zhu Li[6], William Strauss[6]
[1]Hôpital du Sacré-Coeur de Montréal, Université de Montréal, Montréal, QC, Canada, [2]York Central Hospital, Richmond Hill, ON, Canada, [3]Royal Victoria Hospital, McGill University, Montreal, QC, Canada, [4]St Paul's Hospital, University of British Columbia, Vancouver, BC, Canada, [5]Renal Unit, King's College Hospital, London, United Kingdom, [6]AMAG Pharmaceuticals, Inc., Lexington, MA

BACKGROUND: Few randomized controlled trials have compared IV iron preparations head-to-head in CKD patients (pts) with iron deficiency anemia (IDA). This openlabel study compared the efficacy and safety of two marketed IV irons (ferumoxytol [FER] and iron sucrose [IS]) in pts with CKD.

METHODS: Pts were randomized 1:1 to either 1.02 g FER (2 x 510 mg injections) or 1.0 g IS (10 x 100 mg slow injections or infusions for hemodialysis [HD] pts and 5 x 200 mg slow injections or infusions for nondialysis pts). Main inclusion criteria included hemoglobin (Hgb) <11.0 g/dL and TSAT <30%. Pts with a history of allergy to IV iron and Hgb ≤ 7g/dL were excluded.

RESULTS: Overall, 162 pts were randomized (80 FER; 82 IS). Canadian sites entered 21 pts; 12 treated with FER and 9 with IS. Demographics were balanced between the two treatment groups; approximately 43% of pts were on HD. Key adverse event (AE) categories are presented below (cf Table). The mean change in Hgb from Baseline to Week 5 for FER-treated pts was 0.71 g/ dL vs 0.61 g/dL for IStreated pts. Additionally, 50% of pts treated with FER achieved a ≥1 g increase in Hgb from Baseline to Week 5 compared to 42% of IS-treated pts.

CONCLUSIONS: In this randomized controlled trial, FER demonstrated comparable efficacy and a favorable safety profile relative to IS. The lower rate of AEs in the FER group may relate to fewer IV iron exposures required to deliver 1 gram of iron with FER relative to IS (2 vs 5 or 10). The fewer administrations with FER may translate into clinical resource savings.