EFFICACY OF DARBEPOETIN ALFA (DA) IN HEMODIALYSIS (HD) PATIENTS.

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Aim: DA has three times the half-life of recombinant human erythropoietin (EPO). Aim of the study was to evaluate the efficacy and safety of DA in prevalent HD patients (pts) converted from EPO to DA. Efficacy was determined as goal hemoglobin (HB) above 11 g/dL

Methods: Study design included the administration of DA over 10 months (11/2006-09/2007). All HD pts (mean HB 11.8 g/dL) on maintenance EPO were converted to DA. DA was administered intravenously weekly and HB monitored weekly. Dosage of DA was adjusted monthly to maintain HB between 11 and 13 g/dL. Serum ferritin (SF), iron saturation (IS), Kt/V, iPTH, and serum albumin (SA) were measured monthly.

Results: Total pts enrolled 161. Demographics: a) mean age, 62.5 yrs; b) gender: female, 52.3%; and c) ethnicity, African-American, 68.5%. Causes of ESRD: diabetes 34.5%, hypertension 29.8%, GN 7.6%, and unknown 28%. Mean lab data reported SF 541 ng/mL, IS 29%, Kt/v 1.59, iPTH 524pg/mL and SA 3.7 g/dL. At 6 months 73.6% of pts achieved a HB > 11 g/dL. At 10 months 79.6% of pts achieved the target HB range, with mean HB 11.9 g/dL and mean DA dose 400.5 mcg/mo, compatible to the pre-study mean HB of 11.8 g/dL in 81.1% of pts over 12 mo. Pre study mean EPO dose was 76,625 units/mo, giving an EPO to DA conversion ratio of 191.

Conclusion: DA is efficacious in achieving target HB > 11 g/dL in prevalent HD pts, using a weekly-dosing strategy. Pts were able to tolerate the agent without major side effects.