

**THE EFFECT OF BASELINE ESTIMATED GLOMERULAR FILTRATION RATE (eGFR) AND DIABETIC STATUS ON THE EFFICACY OF DARBEPOETIN ALFA IN SUBJECTS WITH CHRONIC KIDNEY DISEASE (CKD)**

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Darbepoetin alfa is an erythropoiesis stimulating agent (ESA) used to treat the anemia associated with CKD. Darbepoetin alfa has greater biological activity than recombinant human erythropoietin (rHuEPO), allowing for extended dosing intervals. Previous studies indicate that darbepoetin alfa administered every other week (Q2W) or once monthly (QM) is effective in maintaining hemoglobin (Hb) levels within target range. This analysis was conducted to explore the hypothesis that Q2W or QM darbepoetin alfa is effective in maintaining Hb levels regardless of baseline eGFR and diabetic status.

Subjects were included in the study if they were  $\geq 18$  years of age, had an eGFR  $\geq 15$  and  $\leq 60$  mL/min/1.73m<sup>2</sup>, were not receiving dialysis, and were receiving every-week (QW), Q2W, or QM rHuEPO or Q2W or QM darbepoetin alfa. Subjects were converted to or continued receiving Q2W or QM darbepoetin alfa based on the previous treatment they were receiving. Darbepoetin alfa doses were adjusted to maintain a Hb level  $\geq 11$  g/dL and  $\leq 13$  g/dL. Hb levels for this 52-week study were assessed over weeks 25-33. The effects of baseline eGFR and diabetic status on achieving a Hb response were analyzed.

A total of 524 subjects enrolled in this study; 52% were female, 69% were white, and the mean  $\pm$  SD age was  $68 \pm 12$  years. For subjects dosed Q2W or QM darbepoetin alfa, analysis using a univariate model indicated that there was no significant effect of baseline eGFR (Q2W,  $P=0.53$ ; QM,  $P=0.61$ ) or diabetic status (Q2W,  $P=0.47$ ; QM,  $P=0.36$ ) on achieving a Hb response. No significant effects on achieving a Hb response were also observed using a multivariate model which included baseline Hb (Q2W,  $P=0.50$ ; QM,  $P=0.09$ ), diabetic status (Q2W,  $P=0.47$ ; QM,  $P=0.33$ ), and baseline eGFR (Q2W,  $P=0.58$ ; QM,  $P=0.59$ ).

These results demonstrate that darbepoetin alfa dosed Q2W or QM is effective in maintaining Hb levels in the target range regardless of the diabetic status and baseline eGFR levels of CKD subjects who were not receiving dialysis.