EXHIBIT C

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Randomized Comparison of IV C.E.R.A. (Continuous Erythropoietin Receptor Activator) and Darbepoetin Alfa (DA) at Extended Administration Intervals for the Maintenance of Hb Levels in Patients with CKD on Dialysis: Rationale and Design.

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C.E.R.A., a new erythropoietic agent acting differently at the receptor level with a prolonged half-life of approximately 130 h, has been shown to correct anemia and maintain stable Hb levels at extended administration intervals of up to once monthly (QM) in CKD patients. This study will compare IV C.E.R.A. and DA administered at extended intervals for Hb maintenance in hemodialysis patients.

A total of 488 iron-replete patients (≥18 yr) with baseline Hb 11.0-13.0 g/dL on previous maintenance therapy with IV DA 1x/wk will be randomized 1:1 to receive either IV C.E.R.A. QM or IV DA 1x/2wk for 26 wk. Doses of C.E.R.A. and DA will be titrated to maintain Hb at 11.0-13.0 g/dL. At wk 27, patients on C.E.R.A. will continue with C.E.R.A. QM, whereas those on DA will switch to QM administration. Patients in either group with Hb below 10 g/dL or Hb decline of ≥2.5 g/dL from baseline values after wk 35 will be withdrawn. The primary endpoint will be the proportion of patients with average Hb ≥10.5 g/dL and average change from baseline ≥-1.0 g/dL assessed during wk 50-53 (C.E.R.A. QM vs DA QM). The study has 90% power to demonstrate a 15% difference in the primary endpoint at the 5% significance level. Enrolment will start in Q4 of 2006 with first results expected in Q3 of 2008. The study will establish the feasibility of converting hemodialysis patients from DA to C.E.R.A. and will compare the efficacy of the two agents for Hb maintenance at extended administration intervals.

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