EXHIBIT 5

SA-PO205

IV C.E.R.A. (Continuous Erythropoietin Receptor Activator) Once Every 2 Weeks or Once Monthly Maintains Stable Hb Levels after Converting Directly from IV Epoetin 1-3 Times Per Week in Patients with CKD on Dialysis.

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C.E.R.A., an innovative agent with different binding properties compared to epoetin and a prolonged half-life, is in development for correction of anemia and maintenance of Hb at extended administration intervals in CKD patients. This study examined the efficacy of IV C.E.R.A. up to once monthly in maintaining stable Hb levels in dialysis patients converted directly from IV epoetin 1-3x/wk.

This multicenter study included dialysis patients (≥18 yr), on stable doses of IV epoetin (1-3x/wk), with stable baseline Hb (10.5-13.0 g/dL) and adequate iron status. Patients were randomized to continue IV epoetin (n=226) or to IV C.E.R.A. 1x/2wk (n=223) or 1x/4wk (n=224) for 52 wk. Dose was adjusted (no more frequently than 1x/4wk) to maintain Hb within 1.0 g/dL of baseline level and within 10.0-13.5 g/dL. Patients were evaluated during wk 29-36 and followed up during wk 37-52.

Mean (SD) Hb levels were comparable in all groups at baseline (range, 11.9-12.0 [0.6-0.7] g/dL) and during evaluation (range, 11.7-11.8 [1.0-1.1] g/dL) and follow-up (range, 11.6-11.8 [1.0] g/dL). SD of the means indicated comparable inter-patient variability in Hb between groups. Within patient mean SD values for Hb during evaluation and follow-up were 0.60 g/dL and 0.79 g/dL, respectively, for C.E.R.A. 1x/2wk; 0.56 g/dL and 0.71 g/dL for C.E.R.A. 1x/4wk; and 0.55 g/dL and 0.66 g/dL for epoetin, indicating comparable intra-patient variability in Hb across groups.

In summary, once-monthly IV C.E.R.A. provided stable Hb levels, as recommended by guidelines, over the long term in patients converting directly from epoetin 1-3x/wk. These data also indicate that C.E.R.A. maintains tight control of Hb when administered at extended intervals.

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SA-PO207

SC C.E.R.A. (Continuous Erythropoietin Receptor Activator) Once Every 2 Weeks or Once Monthly Maintains Stable Hb Levels after Converting Directly from SC Epoetin 1-3 Times Per Week in Patients with CKD on Dialysis.

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C.E.R.A., an innovative agent acting differently at the receptor and with a prolonged half-life, is in development for correction of anemia and maintenance of Hb at extended administration intervals in CKD patients. This study examined the efficacy of SC C.E.R.A. up to once monthly in maintaining stable Hb levels in dialysis patients converted directly from SC epoetin 1-3x/wk.

This multicenter study included dialysis patients (≥18 yr), on stable SC epoetin (1-3x/wk), with stable Hb (10.5-13.0 g/dL) and adequate iron status. Patients (n=572) were randomized to continue on SC epoetin (n=191) or to SC C.E.R.A. 1x/2wk (n=190) or 1x/4wk (n=191) for 52 wk. Dose was adjusted to maintain Hb ±1.0 g/dL of baseline and within 10.0-13.5 g/dL. Patients were evaluated in wk 29-36 and followed up during wk 37-52.

Mean (SD) Hb levels were the same at baseline in all groups (11.7 [0.7] g/dL) and remained stable during evaluation (range, 11.4-11.7 [1.1-1.2] g/dL) and follow-up (range, 11.5-11.6 [1.0-1.1] g/dL) periods. SD of the means indicated comparable inter-patient variability in Hb between groups. Within patient mean SD values for Hb during evaluation and follow-up were 0.52 & 0.68 g/dL, respectively, for C.E.R.A. 1x/2wk; 0.57 & 0.76 g/dL for C.E.R.A. 1x/4wk; & 0.57 & 0.68 g/dL for epoetin, indicating comparable intra-patient variability in Hb across groups.

These Phase III results show that once monthly SC C.E.R.A. provided long-term tight control of Hb, as recommended by guidelines, in patients converting directly from epoetin 1-3x/wk over the long term. By maintaining Hb within a tight range, once-monthly C.E.R.A. will decrease the time and effort needed for anemia management.

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SA-PO212

C.E.R.A. (Continuous Erythropoietin Receptor Activator) Administered at Extended Intervals Corrects Hb Levels in Patients with CKD on Dialysis. M. Klinger,[1] M. Arias,[2] V. Vargemezis,[3] A. Besarab,[4] W. Sulowicz,[5] T. Gerntholtz,[6] K. Ciechanowski,[7] F. C. Dougherty.[8] *[1]Medical University, Wroclaw, Poland; [2]Hospital Marques de Valdecilla, Santander, Spain; [3]University Hospital, Alexandroupolis, Greece; [4]Henry Ford Hospital, Detroit; [5]Jagiellonian University, Crakow, Poland; [6]Chris Hani Baragwanath Hospital, Johannesburg, South Africa; [7]Pomeranian Medical University, Szczecin, Poland; [8]F. Hoffmann-La Roche Ltd, Basel, Switzerland.*

C.E.R.A., an innovative agent with unique receptor activity and a prolonged half-life, is currently in development to provide correction of anemia and stable maintenance of Hb levels at extended administration intervals in CKD patients. This study examined the efficacy of IV C.E.R.A. at extended administration intervals of 1x/2wk in correcting anemia and maintaining Hb levels in ESA-naïve patients with CKD on dialysis.

This multicenter, open-label, parallel-group study enrolled patients (≥18 yr) with CKD on maintenance dialysis (178 on hemodialysis, 3 on peritoneal dialysis) whose baseline Hb was 8–11 g/dL and who had adequate iron status (K/DOQI, EBPG). After screening, patients (n=181) were randomized (3:1) to IV C.E.R.A. (n=135) or epoetin alfa or beta (n=46) for 24 wk. Dose was adjusted to achieve a Hb response (≥1 g/dL increase and ≥11 g/dL). The primary efficacy parameter was the Hb response rate at the end of the correction period of 24 wk.

Mean (SD) Hb levels at baseline were similar for C.E.R.A. (9.4 [0.9] g/dL) and epoetin (9.4 [0.8] g/dL). Response rates (95% CI) at the end of the correction period were 93.3% (87.7-96.9) for C.E.R.A. and 91.3% (79.2-97.6) for epoetin; mean Hb levels were 12.1 g/dL & 12.0 g/dL, respectively. Median dose at the time of response was 0.6 µg/kg/2wk for C.E.R.A. and 123 IU/kg/wk for epoetin. C.E.R.A. was well tolerated; the most frequent AEs were hypertension, procedural hypotension and arteriovenous fistula site hemorrhage. AEs were similar with epoetin.

This Phase III study demonstrated that IV C.E.R.A 0.6 µg/kg/2wk is effective in correcting Hb levels in ESA-naïve patients with CKD on dialysis, achieving target Hb levels (as recommended by guidelines) in more than 90% of patients.

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