

PUB263

Maintenance of Hemoglobin Levels with Once-Monthly C.E.R.A. in Chronic Kidney Disease Patients – Data from the MORAL Study, a Phase IIIb, Single Arm, Open Label Study Neval Duman, Abdullah Uyanik, Abdulkadir Unsal, Siren Sezer, Taner Camsari, Mustafa Cirit, Mehmet Emin Yilmaz, Bulent Altun, Murat Duranay, Alaattin Yildiz, Idris Sahin, Ayhan Dogukan, Sedat Ustundag, Ibrahim Karayaylali, Arzu Kahveci, Sukru Sindel, Yavuz Yenicerioglu, Ahmet Alper Kiykim, Ertugrul Akbas, Fatih Ozdener. *Ankara Univ. School of Med.*

Background: MORAL study was conducted to assess the long term maintenance of hemoglobin (Hb) levels, with once-monthly IV administration of continuous erythropoietin receptor activator (C.E.R.A.) in patients with chronic kidney disease (CKD) previously treated with other erythropoiesis stimulating agents (ESAs) and to evaluate safety and tolerability.

Methods: This study consisted of a 4-week Study Verification Period (SVP), a 16-week Dose Titration Period (DTP), an 8-week Efficacy Evaluation Period (EEP) and a 4-week follow-up period.

Results: Totally 173 patients were screened in the SVP, 132 of which entered the DTP and 107 the EEP. Forty-four patients reported 73 adverse events, 15 of which were serious. Hypertension and bronchitis were the most frequent adverse events reported, occurring in 3.8% and 2.3% of patients, respectively. Two treatment-related serious adverse events were reported and both resolved.

Table 1. Study results

ITT n=127 PP n=84

Mean (SD) BL Hb concentration

g/dL 11.1 (0.56) 11.1 (0.54)

Mean (SD) EEP Hb

concentration g/dL 11.3 (1.06) 11.3 (1.07)

Hb concentration \pm 1 g/dL of

baseline & within 10-12 g/dL

during EEP n (%)

44 (34.7) 39 (46.4)

Hb concentration 10-12 g/dL

during EEP n (%) 65 (51.2) 54 (64.3)

Mean (SD) change in Hb

concentration from baseline g/dL 0.29 (1.08) 54 (64.3)

Median time in target range days 38 38

Conclusions: The results of this study further demonstrate that once-monthly C.E.R.A. administration maintains Hb levels within the target range. The data contributes to the clinical efficacy and safety experience of once-monthly C.E.R.A. in clinical practice.

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