Preliminary Results From a Long-Term Extension Study With Hematide™, a Potential Maintenance Treatment of Anemia in Patients With Chronic Kidney Disease

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Purpose: Hematide™ is a synthetic, peptidic erythropoiesis-stimulating agent (ESA) that is in Phase 3 development for the treatment of anemia associated with chronic kidney disease (CKD). Preliminary results (up to Month 12) from this ongoing long-term study with once-monthly Hematide were previously reported (ANNA National Symposium, 2009); data from an updated analysis (up to Month 24) are reported herein.

Sample: Eighty-one adult patients with CKD who are receiving hemodialysis and who received ≥24 weeks of Hematide treatment in an initial study have been enrolled.

Methods: An open-label safety and tolerability extension study during which Hematide is administered intravenously Q4W. The Hematide dose is adjusted as necessary to maintain a hemoglobin (Hb) level of 10 to 12 g/dL (updated from the original 2006 protocol target of 11 to 13 g/dL).

Results: Mean Hb levels were 11.6 g/dL at baseline (ie, entry into the initial study) and 11.5 g/dL at last assessment (Figure). Patients received a mean of 3.7 (SD, 1.5) dose adjustments per year. Eight patients (10%) had 14 AEs possibly related to Hematide. Serious AEs were reported in 61 patients (75%). Deaths were reported in 16 patients (20%). A single patient experienced a serious AE that was considered Hematide related (pulmonary embolism that lead to death).
**Conclusion:** Preliminary results from this study show that once-monthly Hematide treatment was generally associated with the maintenance of mean Hg levels within 1 g/dL from baseline over a long duration of treatment. Compared with ESAs that are administered more frequently, once-monthly Hematide—if approved—could result in considerable savings in terms of resources and time (Schiller et al, 2008) thereby allowing for greater focus on direct patient care.

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