INTERIM EVALUATION OF LONG-TERM SAFETY AND TOLERABILITY OF HEMATIDE™ DURING MAINTENANCE TREATMENT OF ANEMIA IN PATIENTS WITH CKD ON HEMODIALYSIS. R Geronemus, M Kaplan, P Pergola, B Schiller, F Whittier, S Wright, R Zabaneh, S Zeig, AM Duliege, R Leong, and A Besarab for the AFX01-09 Study Group. Hematide is being developed for treatment of anemia associated with CKD and chemotherapy-induced anemia in patients with cancer. This ongoing, open-label, long-term, roll-over study is evaluating the safety and tolerability of up to 18 months of Hematide during maintenance treatment of anemia in patients with CKD on hemodialysis (HD). Patient eligibility included receipt of Hematide (≥ 24 weeks) in a previous Phase 2 open-label multi-dose study and one Hb value ≥ 10.0 g/dL in the 4 weeks prior to study entry. Patients receive Hematide via the same route (IV) and frequency (every 4 weeks [Q4W]) used at the end of the previous study. Eighty-one patients (mean age: 60 years; 54% male) were enrolled in the study and monitored for adverse events (AEs), Hb concentration, dose adjustments, vital signs, and laboratory values. The mean Hb at baseline was 11.6 g/dL and 11.5 g/dL at 12 months. The mean Hematide starting dose was 0.090 mg/kg, adjusted as needed, with a mean value of 0.085 mg/kg at 12 months. AEs were reported by 78% of patients (most frequently iron deficiency [14%] and upper respiratory tract infection [12%]); serious AEs were reported by 30% of patients (most frequently congestive heart failure [4%] and gangrene [4%]), no serious AEs were related to Hematide; only 1 non-serious AE (insomnia) was considered related to Hematide. In this ongoing long-term study, Q4W dosing of Hematide was well tolerated and maintained stable mean Hb concentrations between 11 and 12 g/dL.