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Objective: To describe the safety, renal, and bone parameters associated with the use of sotatercept (ACE-011), a novel protein that augments the efficacy of EPO by preventing its degradation.

Methods: A single-center, double-blind, placebo-controlled, randomized trial was conducted in 44 subjects with chronic kidney disease (CKD) stage 5D on hemodialysis. Patients were randomized (3:1) to receive placebo or escalating dose levels of sotatercept (0.3, 0.5, or 1.0 mg/kg). The safety population included patients with ≥1 dose of study medication. The renal parameter population included patients who completed the 225-day treatment phase. Safety outcomes were assessed in the safety population. Efficacy was assessed in the renal parameter population.

Results: Patients were randomly assigned to placebo (n = 13) or sotatercept (0.3 mg/kg [n = 13], 0.5 mg/kg [n = 14], and 1.0 mg/kg [n = 14]). No dose-limiting toxicities were observed during the 225-day treatment phase. One patient in the placebo group withdrew consent and one patient in the 0.3 mg/kg group withdrew consent. A total of 40 patients completed the 225-day treatment phase. No significant between-group differences were found in the change from baseline in the safety population for renal parameters.

Conclusions: The safety population was too small to allow meaningful conclusions regarding efficacy. Treatment with sotatercept for 225 days was generally well-tolerated, and no dose-limiting toxicities were observed.