Safety and Hemoglobin Effect of the First 28-Day Dose Cycle of Sotatercept 0.7 mg/kg Compared With Lower Doses and Placebo for Correction of Anemia in Hemodialysis Subjects: Interim Analysis

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INTRODUCTION

This 2-part, phase 2A, randomized, placebo-controlled study is the first trial to evaluate the pharmacokinetics (PK), safety, and hemoglobin (Hb) levels ranging from 13.0 to 15.0 g/dL. of SC sotatercept for the correction of ESKD-related anemia.

METHODS

Presence of hypertension, diabetes, and hemoglobin and each variable (%): cardiovascular disease, diabetes, and Hb were used to stratify subjects into tertiles. The dose-dependent increase in Hb was assessed using paired t-tests. The per-protocol population excludes data from those subjects with protocol violations and are censored for those subjects who had treatment failure requiring rescue in the first dose cycle. The per-protocol population was defined as subjects receiving placebo, or sotatercept 0.3, 0.5, and 0.7 mg/kg, respectively. Baseline Hb levels in the per-protocol population were similar to the full analysis set (baseline Hb levels ≥10 g/dL).

RESULTS

The PK parameters for sotatercept at 0.3, 0.5, and 0.7 mg/kg were consistent with those previously reported. The half-life of sotatercept was approximately 21 to 26 days (Table 3), suggesting the need for a dosing regimen of once every 2 weeks instead of the once every 4 weeks used in this study.

CONCLUSIONS

Sotatercept exhibited dose linear PK characteristics, and a half-life of 21 to 26 days. This interim analysis indicates adequate and dose-dependent Hb responses and safety of sotatercept at 0.3, 0.5, and 0.7 mg/kg. Treatment with sotatercept 0.7 mg/kg resulted in a dose-dependent increase in Hb levels and was well tolerated in this pooled analysis of subjects receiving sotatercept 0.3, 0.5, and 0.7 mg/kg, respectively.

REFERENCES