Sotatercept Improves Anemia, Vascular Calcification, and Bone Loss in Patients With End-Stage Kidney Disease on Hemodialysis

John Havel*, Nelson Kopcy*, Daniel Coyne*, Michael Weisnauer†, William T. Smith‡

**Abstract**

Sotatercept (ACE-011) is a type II activin A receptor (ActRIIA)-IgG1 fusion protein that binds with high affinity to activin A βsuperfamily; by blocking signaling through the ActRIIA receptor, sotatercept can reduce vascular calcification.

**Methods**

Subjects were randomized to escalating dose levels of sotatercept (0.3 mg/kg, 0.5 mg/kg, or 0.7 mg/kg SC) or placebo every 28 days for up to 8 dose cycles or until Hb dropped below 11 g/dL. Low-level anti-drug antibody titers developed in one subject without consequence to PK, Hb effect, or safety.

**Results**

Sotatercept doses of 0.3 mg/kg and 0.5 mg/kg increased plasma sotatercept concentrations over time, whereas placebo concentrations remained low. Sotatercept doses of 0.3 mg/kg and 0.5 mg/kg increased Hb by ≥1 g/dL compared with placebo. A Hb response ≥1 g/dL was noted in 60% of subjects on 0.3 mg/kg and 50% on 0.5 mg/kg. The increase in Hb was sustained for 99.4 days after the last treatment visit in the safety population (mean change in SBP: –0.1, 5.2, 4.7, –1.4, and –4.0 mm Hg, respectively; mean change in DBP: 2.4, 4.8, 5.7, 1.1, and 3.1 mm Hg, respectively).

**Conclusions**

Sotatercept was well tolerated over 225 days (up to eight 28-day dose cycles), with an acceptable safety profile in the overall population. The increase in Hb from baseline was sustained for 99.4 days after the last treatment visit in the overall population. The increase in Hb was sustained for 99.4 days after the last treatment visit in the overall population.

**References**


4. Presentations of additional abstracts concerning sotatercept were also made at the meeting. Abstracts are available online at http://www.asnepn.org/meetings/kidneyweek/2015/abstracts.htm.

**Corresponding Author:**

John Havel, MD
Celgene Corporation
380 Park Ave South
New York, NY 10016
Phone: 212-359-2100
Email: John.Havel@celgene.com