ANNA
AMERICAN NEPHROLOGY NURSES' ASSOCIATION

ANNA's 43RD NATIONAL SYMPOSIUM
APRIL 29-MAY 2, 2012
WALT DISNEY WORLD DOLPHIN, ORLANDO, FL

Safety of Peginesatide for Managing Anemia in Dialysis Patients

Cheryl Dalton, BSN, RN, CNN, CCRC[1], Sheila Doss-McQuitty, BSN, RN, CNN, CCRA[2], Hina Patel, PharmD[3], Hong Tang, MS[3], Daniel Cooper, MD[3]
[1]West Virginia University, Department of Medicine, Nephrology, Morgantown, WV; [2]Satellite Healthcare, San Jose, CA; [3]Affymax, Inc., Palo Alto, CA

Purpose: Peginesatide is a synthetic, PEGylated, investigational, peptide-based erythropoiesis-stimulating agent (ESA) that stimulates the erythropoietin receptor. Two Phase 3 trials were conducted to assess the safety and efficacy of peginesatide compared to epoetin alfa/beta (EMERALD 1 and 2). This analysis evaluated cardiovascular and ESA class adverse events (AEs) in patients on dialysis.
Methods: 1608 patients on dialysis were enrolled in two randomized, open-label trials comparing peginesatide (once monthly) with epoetin (1-3 times weekly). Primary analysis of CV events assessed by a blinded independent Event Review Committee showed similar rates in each group; here other CV and ESA class AEs were evaluated.
Results: Both peginesatide and epoetin groups had similar rates of AEs (95% vs 93%), serious AEs (54% vs 57%), CV AEs and ESA class AEs (Table), and deaths (8.7 vs 9.5 deaths per 100 patient follow-up years). There were no clinically relevant differences between groups in lab parameters, including platelet counts or blood pressure levels.

Table.

Event, N (%)	Peginesatide (N=1066)	Epoetin (N=542)
Cerebrovascular Disorders	45 (4%)	40 (7%)
Cardiac Failure	229 (22%)	116 (21%)
Cardiac Arrhythmias	210 (20%)	123 (23%)
Ischemic Heart Disease*	118 (11%)	67 (12%)
Hypertension	208 (20%)	101 (19%)
Thromboembolic Events		
Arterial	71 (7%)	48 (9%)
Venous	21 (2%)	9 (2%)
Vascular Access Complications	193 (18%)	107 (20%)
Convulsions	23 (2%)	11 (2%)
Infusion/Injection-related Reactions	32 (3%)	11 (2%)
Malignancy	41 (4%)	23 (4%)

*Includes myocardial infarction and unstable angina.

Conclusion: Once-monthly peginesatide and epoetin 1-3 times weekly had similar rates of CV and ESA class AEs in these studies.

Abstract selected for presentation at ANNA's 43rd National Symposium, Orlando, FL, 2012