[2671] The Efficacy and Safety of Darbepoetin Alfa for Treating Anemia in Low-Risk Myelodysplastic Syndrome Patients: Results after 53/55 Weeks. Session Type: Poster Session, Board #849-II

Janice Gabrilove, Ronald Paquette, Roger M. Lyons, Chaudhry Mushtaq, Mikkael A. Sekeres, Hung Lam, Lyndah Dreiling Dept of Medicine, Mt. Sinai School of Medicine, New York, NY, USA; Oncology Center, UCLA, Los Angeles, CA, USA; Medical Oncology, Cancer Care Centers of South Texas/US Oncology Research, San Antonio, TX, USA; Medical Oncology, South Carolina Oncology Associates, Columbia, SC, USA; The Taussig Cancer Center, The Cleveland Clinic, Cleveland, OH, USA; Medical Affairs, Amgen Inc, Thousand Oaks, CA, USA

Myelodysplastic syndromes (MDS) are hematopoietic disorders characterized by peripheral cytopenias and risk of progression to leukemia. MDS patients (pts) are often anemic, resulting in increased red blood cell transfusions (tfns) and fatigue. Previous studies have shown that 150mcg/week (wk) or 300mcg/wk of the erythropoiesis-stimulating agent (ESA) darbepoetin alfa (DA) can raise hemoglobin (Hb) levels in low-risk MDS pts (*Patton et al. J Support Oncol. 2005;3:419-426*). We present data from a phase 2, single-arm, open-label study on the efficacy of 500mcg DA administered every three wks (Q3W) for treating anemia in low-risk MDS pts. Eligibility criteria included ≥18 years, anemia (Hb ≤11g/dL), and low- or intermediate-1-risk MDS (IPSS definition). If pts did not respond by wk 7, the dosing frequency was escalated to Q2W. After the last DA dose on wk 52, the end of study (EOS) was wk 53 (Q2W dosing) or wk 55 (Q3W dosing). The primary endpoint was the percentage of pts with an erythroid response (International Working Group criteria) by wk 13. Secondary 53/55-wk endpoints included incidence of erythroid responses, incidence of tfns, and the change in Hb levels and FACT-F score from baseline (BL). Results were stratified by whether pts had prior ESA therapy: ESA-naive (ESA-N) vs prior ESA-treated (ESA-T). A previous interim analysis showed that low-risk MDS pts could achieve an erythroid response after 13 wks of DA 500mcg Q3W (*Gabrilove et al. Blood. 2005;106:abstract2541*). This is the first reported summary after 53/55 wks (n=148). Of 98 ESA-N pts, 47% were men, 85% were white, and the mean (SD) age was 74 (10) years; the 50 ESA-T pts had similar demographics. Both ESA-N and ESA-T pts had similar BL Hb (Table). By wk 53/55, the percentage (95% CL) of pts with a major erythroid response (≥2g/dL Hb rise from BL or tfn independence) was 56% (46, 66) in ESA-N pts and 30% (17, 43) in ESA-T pts. Both ESA-N and ESA-T pts had a clinically meaningful rise (≥3 points) in FACT-F score from BL. Of the 148 pts, 89% reported adverse events (AEs) with the most common AE being fatigue, 7% had AEs considered related to DA treatment, and 1.4% had thromboembolic events. These results suggested that DA 500mcg Q3W was well tolerated and increased Hb levels in the MDS pts in this study.

	ESA-N, N=98	ESA-T, N=50
Crude % (95% CL) pts with a major erythroid response	56% (46, 66)	30% (17, 43)
Crude % (95% CL) pts with a minor erythroid response	15% (8, 22)	20% (9, 31)
Mean (SD) BL Hb, g/dL	9.8 (1.0) [n=84]	10.0 (1.2) [n=41]
Mean (SD) Hb change (BL to wk 53/55) (last value carried forward)	1.1 (1.6) [n=84]	0.2 (1.7) [n=41]
Crude % (95% CL) pts achieved target Hb (11g/dL)	68% (58, 78) [n=87]	46% (31, 60) [n=46]
Mean (SD) Hb after reached Hb target, g/dL	11.7 (0.8) [n=68]	11.6 (0.9) [n=25]
KM% (95% CL) pts with tfns (wk 1 to EOS)	29% (19, 39)	43% (27, 59)
KM% (95% CL) pts with tfns (wk 5 to EOS)	28% (19, 38) [n=96]	43% (26, 60) [n=45]

Mean (SD) change in FACT-F score (BL to wk 53/55)	5.8 (8.6) [n=45]	7.2 (9.3) [n=15]

KM%= Kaplan-Meier percentage

Abstract #2671 appears in Blood, Volume 108, issue 11, November 16, 2006
Keywords: Hemoglobin|Erythropoieisis|Clinical trial

Sunday, December 10, 2006 9:00 AM

Poster Session: Myelodysplastic Syndromes: Treatment (9:00 AM-8:00 PM)