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**Sunday, December 11, 2005 9:15 AM
Poster Session: Myelodysplastic Syndromes: Clinical Studies (9:15 AM-7:30 PM)**

[2541] A Phase 2, Single-Arm, Open-Label Trial To Evaluate the Effectiveness of Darbepoetin alfa for the Treatment of Anemia in Patients with Low-Risk Myelodysplastic Syndrome. Session Type: Poster Session 745-II

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Patients (pts) with myelodysplastic syndromes (MDS) often develop clinically significant anemia due to ineffective hematopoiesis. Using the erythropoiesis-stimulating protein (ESP) epoetin alfa to treat anemia results in an average response rate of approximately 30% (40% when used with G-CSF) in low-risk MDS pts. Darbepoetin alfa (DA) (150 to 300 mcg/week) also effectively increases hemoglobin (Hb) concentrations and reduces red blood cell transfusion requirements in these pts. This study is a phase 2, single-arm, open-label trial (with a planned sample size of 200 pts), evaluating the efficacy of DA 500 mcg given SC every 3 weeks (Q3W) for treating anemia in low-risk MDS pts during the 13-week (wk) test period. Eligible pts had low or intermediate-1 risk MDS (IPSS/FAB criteria), anemia (Hb \leq 11 g/dL), and no previous or ongoing chemotherapy or biologic response modifiers (except for ESPs [stopped \geq 7 days and \leq 1 month before enrollment] and G-CSF [allowed for infection before enrollment]). The primary endpoint is the proportion of pts achieving an erythroid response during the test period. Secondary endpoints include the change in Hb from baseline at wk 13, transfusion incidence, and impact on pt-reported fatigue. This study has completed enrollment and data are available from a planned interim analysis of the first 100 pts; 63 pts were not treated with an ESP before enrollment (ESP-naive ([EN])). Of the EN pts, 51% were female, 81% were white, 73% had low-risk MDS, 22% had intermediate-1 risk MDS, 60% had refractory anemia (RA), 30% had RA with ringed sideroblasts (RARS), and 10% had RA with excess blasts (RAEB). Results for EN pts are shown in the table. Of the 37 pts treated with an ESP before enrollment, the crude percentage (95% CL) with an overall (major plus minor) erythroid response was 36% (20, 53), the crude percentage (95% CL) with a major erythroid response was 21% (7, 35), and the crude percentage (95% CL) that required transfusions during wks 1 to 13 was 32% (17, 48). During the test period, 16% of all pts reported a serious adverse event (none were considered treatment-related). Injection site pain (reported by 4% of pts) was the most common treatment-related adverse event. No thromboembolic events have been reported. Interim results from this fully-enrolled study indicate that DA 500 mcg Q3W appears to be well tolerated and capable of increasing Hb levels in low-risk MDS pts. Final results for the primary endpoint will be presented.

	ESP-Naive Pts, N = 63	No. of Patients Evaluated (n)
Crude % (95% CL) pts with overall erythroid response	77% (66, 88)	57
Crude % (95% CL) pts with major erythroid response	47% (34, 60)	57
Mean (95% CL) baseline Hb	9.9 (9.6, 10.1) g/dL	56
Mean (95% CL) change in Hb at wk 13 (last value carried forward approach)	1.1 (0.8, 1.4) g/dL	56
Crude % (95% CL) pts with transfusions (wks 1 to 13)	17% (8, 27)	63
Mean (95% CL) baseline FACT-F score	29.8 (25.9, 33.8)	46
Mean (95% CL) change in FACT-F score at wk 13 (available data)	5.7 (2.3, 9.0)	41

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