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6, each 8 week cycle x 3) or FLOX (same FULV regimen with oxaliplatin 85 mg/m<sup>2</sup> iv administered on weeks 1, 3, and 5 of each 8 week cycle x 3). A planned secondary endpoint of this study was overall survival 5 years after the completion of accrual. The hazard ratio estimate is from a Cox model stratified by positive nodes (0, 1-3, 4+). The p-value is from a log-rank test stratified by positive nodes.

### Results

The median follow-up for patients who were still alive was 67 months; 75% had at least 5-years of follow-up. Because the number of deaths (560) was fewer than anticipated (700), the power to detect the protocol specified effect size of a 0.214 reduction in the annual death rate was reduced from 0.89 to 0.81. The hazard ratio (FLOX vs. FULV) was 0.853 with 95% CI (0.723, 1.008), a 14.7%

reduction in the risk of death in favor of FLOX.

### Conclusion

There is a trend toward improved survival with the addition of oxaliplatin to weekly FULV (p=0.061) in patients with stage II and III colon cancer with 67 months median follow-up. Overall, there were fewer deaths than had been anticipated. 3 yr survival. ★

## A MULTICENTER PHASE II TRIAL OF THE DECITABINE ALTERNATIVE 5-DAY DOSING REGIMEN: ANALYSIS OF EFFICACY IN VARIOUS SUBGROUPS OF PATIENTS WITH MYELODYSPLASTIC SYNDROMES (MDS).

# [7032]

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### Background

Decitabine is an efficient hypomethylating agent approved by the FDA for the treatment of MDS. In a Phase III trial that studied a 3-day dosing regimen, the overall improvement (IWG 2000: complete response [CR] + partial response [PR] + hematologic improvement [HI]) rate for decitabine was 30% versus 7% in the supportive care arm (Cancer 2006:106:1794); responses were seen in all International Prognostic Scoring System (IPSS) risk groups. A single center Phase II trial in patients (pts) with MDS, examining an alternative outpatient regimen of decitabine administered at 20 mg/m<sup>2</sup> IV over 1 hour once daily for 5 days every 4 weeks, resulted in an overall improvement rate (IWG 2006: CR +

marrow CR (mCR) + PR + HI) of 72% (Cancer 2007:109:265). The purpose of this trial was to examine the efficacy and safety of this alternative dosing regimen in a multicenter setting.

### Methods

This Phase II trial enrolled pts with all FAB classifications of MDS and IPSS scores > 0.5 with an ECOG performance status of 0-2. An expert review of responses according to IWG 2006 criteria was performed.

### Results

Baseline patient characteristics: median age 72 yrs, 11% had secondary MDS, 27% with prior MDS disease-modifying therapy, and 29% had poor risk cytogenetics. The overall improvement rate was similar across IPSS risk groups (Intermediate-1 [n=52]: 50%;

Intermediate-2 [n=23]: 61%; High Risk [n=23]: 43%). 82% of pts who experienced clinical improvement did so by cycle 2. The overall improvement rate was 51% for pts with de novo MDS, 45% for secondary MDS, and 44% for pts who received prior disease-modifying agents. The safety profile was consistent with previous studies.

### Conclusion

This multicenter trial examining the alternative 5-day decitabine dosing schedule compares favorably with that of the 3-day dosing regimen, provides validation and generalizability of the previously published single center trial and confirms that the alternative schedule is safe and effective in pts with MDS including those who have poor prognostic factors. ★