1LB Updated Late Breaking

5-year overall survival update from the X-ACT trial of capecitabine vs. 5-FU/LV as adjuvant treatment for stage-III colon cancer

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Background: Intravenous bolus 5-fluorouracil plus leucovorin (5-FU/LV) is the standard adjuvant treatment for colon cancer. The oral fluoropyrimidine capecitabine is an established alternative to 5-FU/LV as first-line treatment for metastatic colorectal cancer. We evaluated capecitabine vs. 5-FU/LV as adjuvant treatment for early-stage colon cancer.

Materials and Methods: This X-ACT trial randomly assigned 1987 patients with resected stage III colon cancer to oral capecitabine (n = 1004) or bolus 5-FU/LV (Mayo Clinic regimen; n = 983) over 24 weeks. The primary efficacy endpoint was at least equivalence in disease-free survival (DFS); other efficacy endpoints included relapse-free survival (RFS) and overall survival. The primary safety endpoint was the incidence of grade 3/4 fluoropyrimidine toxicities.

Results: At a median follow-up of 3.8 years [see Twelves et al. NEJM 2005; 352: 2696–704], DFS in the capecitabine group was at least equivalent to 5-FU/LV (intent-to-treat analysis, $P < 0.0001$ compared with hazard ratio upper limit 1.20). Capecitabine improved RFS (hazard ratio, 0.86; 95% confidence interval, 0.74 to 0.99; $P = 0.0407$) and was associated with significantly fewer adverse events than 5-FU/LV ($P < 0.001$). With a median follow-up of 7 years, the 5-year overall survival rates were 71.4% (95% CI 68–74%) in the capecitabine group and 68.4% (95% CI 65–71%) in the 5-FU/LV group, corresponding to a HR of 0.86 (95% CI 0.74–1.01).

Conclusions: Previously published results have shown that oral capecitabine is an effective alternative to intravenous 5-FU/LV in the adjuvant treatment of colon cancer. This update shows that capecitabine is at least equivalent to 5-FU/LV with a trend to superiority ($p = 0.06$) in terms of 5-year overall survival in the adjuvant treatment of stage III colon cancer.

Proffered papers session, Gastrointestinal malignancies – colorectal cancer I.
Tuesday 25 September 2007, 09:00–11:15