

Analysis of Post-study Chemotherapy in Patients (pts) Enrolled in the X-ACT Phase III Trial of Capecitabine (X) vs. Bolus 5-FU/LV as Adjuvant Therapy for Dukes' C Colon Cancer

No differences in treatment arms that could influence survival outcome [3586]

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Background: The X-ACT trial evaluated adjuvant X vs. 5-FU/LV in colon cancer. Between Nov98 and Nov01, 1987 pts with resected Dukes' C colon carcinoma were randomized to receive either oral X (1250mg/m² bid d1-14, q3w) or i.v. 5-FU/LV (Mayo Clinic regimen: LV20 mg/m² + 5-FU 425mg/m² d1-5, q4w) for 24 weeks. X was at least equivalent to 5-FU/LV in terms of disease-free survival (DFS), with trends toward superior DFS and overall survival.

Methods: We analyzed post-study chemotherapy in both treatment arms to determine whether there were any differences that could influence survival outcome.

Results: At the time of this analysis, 629 events have occurred. 656 pts in the X and 603 in the 5-FU/LV arm are alive and disease-free, with 148 and 153, respectively, alive with relapse/new recurrence. 277 pts received post-study chemotherapy. Of these, 25 in the X and 10 in the 5-FU/LV arm received adjuvant chemotherapy following

	NUMBER OF PATIENTS	
	X (n=1004)	5-FU/LV (n=983)
Post-study chemotherapy (metastatic):	239	251
Both first- and second-line treatment	92	108
Three or more lines of treatment	42	40
Type of first-/second-line treatment:		
Irinotecan-based	81/29	82/32
5-FU± LV	65/21	61/19
Oxaliplatin-based	57/27	49/31
Other	0/9	0/15

randomization into X-ACT either because they never received study treatment or at the investigator's discretion (after early termination of study treatment for any reason). In addition, 13 pts in the X and 16 pts in the 5-FU/LV arm received post-study chemotherapy for new occurrences of cancer other than colon cancer (breast, prostate, lung) prior to relapse from the primary or a new occurrence of colon cancer. Pts meeting the entry criteria (free of disease at study entry and receiving ≥ 1 doses of study

treatment) who were treated according to the protocol and experienced relapse or new occurrence of colon cancer formed the largest group receiving post-study chemotherapy (table).

Conclusions: These data suggest that there are no differences in post-study chemotherapy that could influence survival outcome in pts who received either X or 5-FU/LV as adjuvant therapy in the X-ACT trial. ●

Updated Efficacy Findings From the X-ACT Phase III Trial of Capecitabine (X) vs. Bolus 5-FU/LV

As Adjuvant Therapy for Patients (pts) with Dukes' C Colon Cancer [3521]

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Background: X is an oral fluoropyrimidine with superior activity and improved safety compared with bolus 5-FU/LV in first-line metastatic colorectal cancer. Based on X's efficacy in advanced disease and the strong pt preference for oral chemotherapy, the X-ACT trial evaluated X vs. 5-FU/LV as adjuvant treatment for colon cancer.

Methods: Pts with resected Dukes' C colon carcinoma were randomized to receive either oral X (1250mg/m² bid on days 1-14, every 3 weeks) or i.v. 5-FU/LV (Mayo Clinic regimen: LV20 mg/m² + 5-FU 425mg/m² days 1-5, every 4 weeks) for 24 weeks. At least equivalence in disease-free survival (DFS) was the primary endpoint.

Results: 1987 pts (1004 to X; 983 to 5-FU/LV) from 164 centers were randomized between Nov 1998 and Nov 2001. Baseline characteristics (median age, ECOG score, sex, nodal status, tumor differentiation, and preoperative CEA values) were well balanced in each arm (p = NS). Here we present data

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