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NCCN Guidelines Panel: Colon/Rectal/Anal Cancers Guideline Panel

On behalf of Genentech, I respectfully request the NCCN Colon/Rectal/Anal Cancers Guideline Panel to review the enclosed data on the use of Xeloda[®] (capecitabine) in combination with oxaliplatin as adjuvant treatment for Stage III (Dukes' C) colon cancer.

Specific Changes: For your information, data have been recently published on Xeloda with oxaliplatin as adjuvant treatment in Stage III colon cancer.

FDA Clearance: Xeloda in combination with oxaliplatin is not FDA-approved for adjuvant treatment for Stage III colon cancer. Xeloda is FDA-approved as a single agent for adjuvant treatment in patients with Dukes' C Colon cancer who have undergone complete resection of the primary tumor when treatment with fluoropyrimidine therapy alone is preferred.¹ Xeloda is indicated as first-line treatment of patients with metastatic colorectal carcinoma when treatment with fluoropyrimidine therapy alone is preferred. Please refer to the enclosed prescribing information for the full FDA-approved indications and safety information.

Rationale: Study NO16968 is a Phase III, randomized, multicenter, open-label trial that compared adjuvant treatment with Xeloda in combination with oxaliplatin (XELOX) against bolus fluorouracil (FU) and folinic acid (FA, leucovorin) in Stage III colon cancer.² The XELOX treatment arm demonstrated significantly superior disease-free survival (DFS), the primary study endpoint, over the fluorouracil and folinic acid arm. Secondary endpoints included overall survival, relapse-free survival and safety. There were 55% of XELOX-treated patients and 47% of FU/FA-treated patients who experienced Grade 3 or 4 adverse events related to treatment ($p < 0.05$).

The following enclosures are included for your review (copyright-paid where applicable):

- Haller DG, Tabernero J, Maroun J, et al. Capecitabine plus oxaliplatin compared with fluorouracil and folinic acid as adjuvant therapy for stage III colon cancer. *J Clin Oncol*. 2011; 29:1465-71.
- Xeloda Prescribing Information

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Cited References

1. Xeloda Prescribing Information
2. Haller DG, Tabernero J, Maroun J, et al. Capecitabine plus oxaliplatin compared with fluorouracil and folinic acid as adjuvant therapy for stage III colon cancer. *J Clin Oncol.* 2011; 29:1465-71.