

Submitted by:
Ellen Yang, PharmD, Scientist
Medical Communications, Medical Affairs
Genentech, Inc.
1 DNA Way
South San Francisco, CA 94080
Phone: (650) 467-0637
Email: yang.ellen@gene.com
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NCCN Guidelines Panel: Esophageal/Gastric Cancers Panel

On behalf of Genentech, I respectfully request the NCCN Esophageal/Gastric Cancers Panel to review the enclosed data on the use of Xeloda[®] (capecitabine) in gastric cancer.

Specific Changes: For your consideration, data have been presented on adjuvant Xeloda[®] (capecitabine) and oxaliplatin for gastric cancer.^{1,2}

FDA Clearance: Xeloda in combination with oxaliplatin is not FDA-approved for gastric 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.³ 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: A Phase III, randomized, open-label, multicenter, international (South Korea, China, and Taiwan) study compared adjuvant Xeloda in combination with oxaliplatin (XELOX) to observation in previously untreated patients with Stage II, IIIa, or IIIb gastric cancer who underwent curative D2 gastrectomy.^{1,2} The primary endpoint was 3-year disease-free survival (DFS). In a pre-planned interim analysis, the 3-year DFS was significantly higher in the XELOX arm compared with the observation arm, respectively. The most common adverse events (>50%) in the XELOX arm were nausea, neutropenia, and peripheral neuropathy.

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

- Bang Y, Kim YW, Yang H, et al. Adjuvant capecitabine and oxaliplatin for gastric cancer: results of the Phase III CLASSIC trial. J Clin Oncol 2011;29. ASCO Abstract #LBA4002.
- Bang Y-J, Kim Y-W, Yang H-K, et al. Adjuvant capecitabine and oxaliplatin for gastric cancer: results of the Phase III CLASSIC trial (LBA4002). Presented at the American Society of Clinical Oncology 2011 Annual Meeting in Chicago, Illinois; June 3-7, 2011. ASCO Oral presentation.
- Xeloda Prescribing Information

Cited References

1. Bang Y, Kim YW, Yang H, et al. Adjuvant capecitabine and oxaliplatin for gastric cancer: results of the Phase III CLASSIC trial. J Clin Oncol 2011;29. ASCO Abstract #LBA4002.
2. Bang Y-J, Kim Y-W, Yang H-K, et al. Adjuvant capecitabine and oxaliplatin for gastric cancer: results of the Phase III CLASSIC trial (LBA4002). Presented at the American Society of Clinical Oncology 2011 Annual Meeting in Chicago, Illinois; June 3-7, 2011. ASCO Oral presentation.
3. Xeloda Prescribing Information