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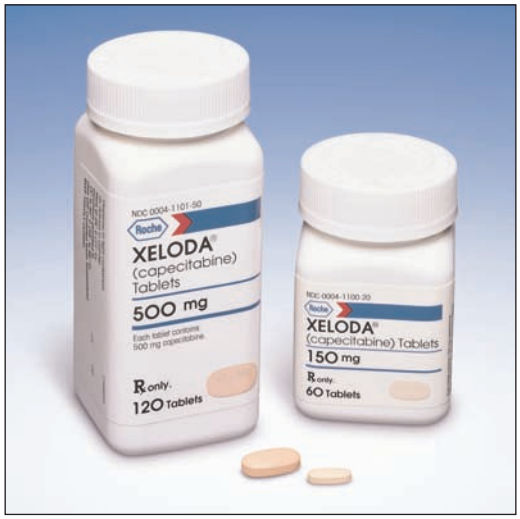
EXPANDED USE OF ORAL CHEMOTHERAPY PILL XELODA® INVESTIGATED IN MULTIPLE TUMOR TYPES

XELODA® (capecitabine) is the only FDA-approved oral chemotherapy for both metastatic breast, and metastatic and adjuvant colorectal cancer. Inactive in pill form, Xeloda is enzymatically activated within the body when it comes into contact with a naturally occurring protein called thymidine phosphorylase, or TP, which transforms Xeloda into 5-FU, a powerfully cytotoxic (cell-killing) drug. Because many cancers have higher levels of TP than normal tissue, more 5-FU is delivered to the tumor, thereby reducing toxicity to the normal tissue.



Since it became available in the United States in 1998, Xeloda has become a foundational treatment for both metastatic breast and metastatic and adjuvant colorectal cancer. Its proven track record as an efficacious, generally well-tolerated and convenient treatment has prompted researchers to study the expanded use of Xeloda in various cancers other than breast and colon. Currently, a phase III study is under way to investigate the addition of Xeloda to standard chemotherapy as a first-line treatment for advanced pancreatic cancer, and early data has revealed positive results. A second phase III study investigating Xeloda as first-line treatment in advanced gastric cancer successfully showed that Xeloda is as effective as the current standard treatment, with the additional benefit of reduced treatment time.

Xeloda for the Adjuvant Treatment of Colon Cancer

In June 2005, the FDA approved Xeloda for the adjuvant treatment of patients with Dukes' C colon cancer, giving patients who have undergone complete resection of the primary tumor the option of an oral chemotherapy when fluoropyrimidine therapy alone is preferred. Although intravenous 5-FU/LV has been the standard of care for patients with Dukes' C colon cancer for 40 years, researchers have long recognized the need for more convenient treatment regimens. The Mayo Clinic regimen can require up to 30 visits over the 24-week treatment course, compared to a minimum of eight visits for patients receiving Xeloda. This latest indication for Xeloda gives patients with colon cancer the option of a more convenient oral chemotherapy, without compromising safety or efficacy.

The adjuvant indication was based on data from the X-ACT (Xeloda in Adjuvant Colon Cancer Therapy) trial. The results of this landmark study, published in the June

2005 issue of the *New England Journal of Medicine*, found Xeloda to be an effective alternative treatment to intravenous 5-FU/LV for patients with Dukes' C colon cancer. In the X-ACT trial, Xeloda met its primary endpoint of non-inferiority to 5- FU/LV for disease-free survival (DFS). The study further revealed that the three-year DFS rates were 64.2 percent for patients treated with Xeloda, compared to 60.6 percent treated with 5-FU/LV. The overall incidence of grade 3-4 toxicities were similar between Xeloda and 5-FU/LV. Neither Xeloda nor combination chemotherapy has been shown to prolong overall survival; combination chemotherapy has demonstrated an improvement in DFS compared to 5-FU/LV.

Xeloda Shown to Extend Survival for Patients with Pancreatic Cancer

An interim analysis of one of the largest phase III studies investigating the first-line treatment of advanced pancreatic cancer revealed that adding Xeloda to standard chemotherapy (gemcitabine) significantly extended patient survival. Data from the study unveiled at the November 2005 European Cancer Conference held in Paris showed significant survival benefit in fighting this aggressive cancer. The randomized study compared the survival of pancreatic cancer patients on a combination of gemcitabine and Xeloda with the survival of patients on gemcitabine monotherapy. Patients receiving combination therapy of gemcitabine and Xeloda lived significantly longer than those with standard therapy alone (median survival 7.4 vs. 6 months, HR=0.80). Further, a higher percentage of patients were alive at 12 months in the group treated with Xeloda plus gemcitabine, compared to those treated with gemcitabine alone (26 percent vs. 19 percent). The most common grade 3-4 adverse events (≥2 percent) in the gemcitabine-Xeloda combination arm included neutropenia, increased white blood cell count, platelets, fatigue, and hand/foot syndrome. The most common adverse events in the gemcitabine arm alone included increased white blood cell count, neutropenia, hemoglobin, fatigue, and nausea and vomiting.

Xeloda Shown to be Effective in Stomach Cancer

In April 2006, Roche announced that the first-ever phase III study investigating Xeloda as first-line treatment in advanced gastric cancer successfully met its primary endpoint. The data show that Xeloda, added to another chemotherapy (cisplatin) is as effective as the current standard treatment (intravenous 5-FU plus cisplatin), in terms of time to disease progression. Patients receive the current standard of treatment in the hospital for five days every three weeks. Xeloda could potentially reduce hospital administration time to a single day, allowing patients more flexibility. Final study results will be revealed at ASCO 2006.

As with any cancer therapy, there is a risk of side effects, and these are usually manageable and reversible with dose modification or interruption.

For full prescribing information call Roche at 1-800-52-6367, or visit the product Web site at www.xeloda.com.