Xeloda® (capecitabine) – New and expanded indications

- On December 14, 2022, the FDA approved new indications and updates to the current indications for Genentech's Xeloda (capecitabine). The new indications include:
    - Treatment of adults with unresectable or metastatic gastric, esophageal, or gastroesophageal junction cancer as a component of a combination chemotherapy regimen.
    - Treatment of adults with HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma who have not received prior treatment for metastatic disease as a component of a combination regimen.
    - Adjuvant treatment of adults with pancreatic adenocarcinoma as a component of a combination chemotherapy regimen.
- The approval of Xeloda for the new indications were derived from studies in the published literature.
- In addition to the new indications, the use of Xeloda for colorectal cancer was expanded to include:
    - Adjuvant treatment of patients with Stage III colon cancer as a single agent or as a component of a combination chemotherapy regimen.
    - Perioperative treatment of adults with locally advanced rectal cancer as a component of chemoradiotherapy.
    - Treatment of patients with unresectable or metastatic colorectal cancer as a single agent or as a component of a combination chemotherapy regimen.
- Xeloda was previously approved for colorectal cancer 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 and as first-line treatment of patients with metastatic colorectal carcinoma when treatment with fluoropyrimidine therapy alone is preferred.
- The expanded uses for Xeloda for colorectal cancer were derived from studies in the published literature.
- Xeloda is also approved for treatment of patients with advanced or metastatic breast cancer as a single agent if an anthracycline- or taxane-containing chemotherapy is not indicated and treatment of patients with advanced or metastatic breast cancer in combination with docetaxel after disease progression on prior anthracycline-containing chemotherapy.
- Xeloda carries a boxed warning for increased risk of bleeding with concomitant use of vitamin K antagonists.

- The recommended dosage regimens for Xeloda were updated including the option for a lower starting dose for patients with metastatic breast cancer. For complete dosing and administration recommendations, refer to the Xeloda drug label.