Xeloda (capecitabine)

Full Safety and Drug Utilization Review Provided in Background Materials

Judith U. Cope, MD, MPH
Office of Pediatric Therapeutics
OC, FDA

Xeloda (capecitabine)

- **First approved in 1998 and indicated for adjuvant colon cancer, metastatic colorectal cancer and metastatic breast cancer.**
- **The safety and effectiveness in pediatric patients have not been established.**
- **This review was prompted by the submission of studies under BPCA. No clinical benefit was demonstrated in two single arm trials in pediatric patients with newly diagnosed brainstem gliomas and high grade gliomas.**

Pediatric Safety & Use Review

16 SAEs including deaths, 4/30/1998 to 8/31/2015

- **3 deaths due to disease progression**
- **13 nonfatal (8 were in Xeloda studies)**
  - **3 in utero exposures**
  - **1 accidental exposure**
  - **3 reports with labeled events including 1 hand and foot syndrome, dehydration and renal failure; 1 irritability and dysarthria; and 1 dysphagia**
  - **6 reports with unlabeled events including 4 CNS necrosis; 1 intracranial hemorrhage; and 1 amnesia**

The pediatric population 0-17 years accounted for <0.5% (36 patients) of total patients with a prescription claim for capecitabine from 9/2011-8/2015.[1]

[1]Symphony Health Solutions' Integrated Dataverse (IDV)™. September 2011- August 2015. Extracted November 2015.

Summary

- No new safety signal identified
- Little use
- Many of the SAEs and deaths were due to the underlying disease or disease progression
- Many of the SAEs are labeled
- Product labeling is appropriate

Xeloda (capecitabine)

FDA will continue its standard ongoing safety monitoring.

Does the Committee concur?