

The following is a message from the FDA's Office of Oncology Drug Products Director, Dr. Richard Pazdur:

On October 2, 2007, FDA expanded labeling and granted regular approval for single-agent cetuximab (Erbix[®], ImClone Systems, Inc.) for the treatment of patients with EGFR-expressing metastatic colorectal cancer (mCRC) after failure of both irinotecan- and oxaliplatin-based chemotherapy regimens. Erbix[®] was initially approved in 2004 under accelerated approval regulations and the study described below verifies the clinical benefit of single-agent Erbix[®] in this patient population.

The study supporting conversion to regular approval was an open-label, multinational study conducted by the NCI-Canada in patients with EGFR-expressing, progressive mCRC following both irinotecan- and oxaliplatin-containing regimens. Five hundred seventy-two patients were randomized (1:1) to best supportive palliative care (BSC) or palliative care plus Erbix[®] administered as an intravenous infusion of 400 mg/m² on the first dose, then 250 mg/m² weekly until disease progression.

Patients randomized to Erbix[®] demonstrated a statistically significant improvement in overall survival (OS) compared to those randomized to best supportive care (median OS: 6.1 vs. 4.6 months; hazard ratio 0.766, p=0.0048, stratified log-rank test). All documented tumor responses (evaluated centrally by NCIC) occurred in patients randomized to Erbix[®] (6.6%); the median response duration was 5.5 months and all were partial responses.

The safety profile observed in this trial was consistent with the previously described safety profile provided in the product label. Full prescribing information, including clinical trial information, safety, dosing, drug-drug interactions and contraindications is available at <http://www.fda.gov/cder/foi/label/2007/125084s103lbl.pdf>.