

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

On September 19, 2007, the U.S. Food and Drug Administration expanded labeling and granted regular approval for single-agent alemtuzumab (Campath[®], Genzyme Corporation) for the treatment of B-cell chronic lymphocytic leukemia (B-CLL). Campath[®] was initially approved in 2001 under accelerated approval regulations and the study described below fulfills the post-marketing commitment to verify its clinical benefit.

The current study randomized 297 B-CLL patients to either Campath[®] (after dose escalation, 30 mg₂ intravenously over 2 hours 3 times/week on alternate days for 12 weeks) or chlorambucil (40 mg/m orally every 28 days for up to 12 cycles.) Patients had Rai stage I – IV, were previously untreated with chemotherapy, and had evidence of progressive disease at entry. Patients receiving Campath[®] experienced a statistically significant improvement in the primary endpoint of progression-free survival (PFS) compared to those receiving chlorambucil (median PFS: 14.6 vs. 11.7 months; hazard ratio 0.58, p=0.0001 two-sided stratified log-rank test). Patients receiving Campath[®] also demonstrated an increased overall response rate (83% vs. 55%; p<0.0001) and an increased complete response rate (24% vs. 2%; p<0.0001) compared to those receiving chlorambucil. No differences were seen in the FDA-requested interim analysis of survival (24 deaths in each arm.)

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/2007/103948s5070lbl.pdf>.