On behalf of Genentech, I respectively request the NCCN Non-Hodgkin’s Lymphoma (NHL) Guideline Panel to review the enclosed data for Rituxan® (Rituximab) plus fludarabine and cyclophosphamide (FC) for the treatment of mantle cell lymphoma (MCL) presented at the 53rd American Society of Hematology (ASH) Annual Meeting on December 10-13, 2011, in San Diego, California.

**Specific Changes:** Consider the recently presented data on Rituxan plus FC for the treatment MCL.

**FDA Clearance:** Rituxan is not FDA-approved for the treatment of patients with MCL. Please refer to the enclosed prescribing information for the full FDA-approved indications and safety information.

**Rationale:** In a Phase III, randomized trial, Rituxan plus FC was compared with FC in newly diagnosed patients with MCL (n=370). Overall survival, the primary endpoint, was significantly longer in the patients who received Rituxan plus FC compared with patients who received FC (hazard ratio=0.73 (95% CI: 0.54-0.97; p=0.03). More patients in the Rituxan plus FC arm experienced Grade 3 or 4 leukopenia, neutropenia, and thrombocytopenia compared with patients on the FC arm. The number of deaths on trial was 113 patients in the FC arm and 91 patients in the Rituxan plus FC arm. A greater number of patients on the FC arm died of disease progression compared with the Rituxan plus FC arm (80 patients vs. 59 patients, respectively).

Additional data on Rituxan in combination with fludarabine-containing regimens, cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP)-based regimens, hyper-fractionated cyclophosphamide, vincristine, doxorubicin, and dexamethasone (HCVAD), and bendamustine as well as Rituxan maintenance in the treatment of MCL has been previously reported.

The following enclosures are included for your review (copyright-paid where applicable):

- Rituxan Prescribing Information
Cited References


