On behalf of Genentech, I respectfully request the NCCN Non-Hodgkin’s Lymphoma (NHL) Guideline Panel to review the enclosed data for Rituxan® (Rituximab) for the treatment of diffuse large B-cell lymphoma (DLBCL).

**Specific Changes:** Consider revising the number of Rituxan treatment cycles to “up to eight cycles” for the treatment of DLBCL based on the recently presented data from the RICOVER-60 trial at the 2011 American Society of Clinical Oncology (ASCO) Annual Meeting and data from three pivotal, Phase III studies on the use of Rituxan in combination with chemotherapy.

**FDA Clearance:** The FDA has approved Rituxan in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (R-CHOP) or other anthracycline-based chemotherapy regimens for the use in patients with previously untreated DLBCL. The recommended dose for Rituxan is 375 mg/m² on Day 1 of each cycle of chemotherapy for up to eight cycles. Please refer to the enclosed prescribing information (PI) for the full FDA-approved indications and safety information.

**Rationale:** Seven-year follow-up data from the RICOVER-60 trial was recently presented at the 2011 ASCO Annual Meeting in Chicago, Illinois. The randomized RICOVER-60 trial evaluated the safety and efficacy of 6 or 8 cycles of CHOP-14 both with and without 8 cycles of Rituxan in elderly patients with DLBCL. All Rituxan containing arms of the RICOVER trial utilized 8 cycles of Rituxan. At both the 3-year and 7-year follow-up, event-free survival and progression-free survival were significantly greater with 6 cycles of CHOP in combination with 8 cycles of Rituxan than with 6 cycles of CHOP alone. At the 7-year follow-up, OS was significantly better with either 6 or 8 cycles of CHOP in combination with 8 cycles of Rituxan than with 6 cycles of CHOP alone at 7 years. The authors concluded that 6 cycles of CHOP in combination with 8 cycles of Rituxan is the preferred regimen for elderly patients with DLBCL. Adverse events were reported at 3 years. There were 92 treatment-related deaths, occurring in 8% (n=50) of the 8-CHOP cycle arms and 7% (n=42) of patients in the 6-CHOP cycle arms. More patients in the 8-CHOP cycle treatment arms experienced anemia, mucositis, red-blood-cell transfusions, and interventional antibiotics compared with those in the 6-CHOP cycle arms.

Additional data from two Phase III studies evaluating 8 cycles of Rituxan in combination with CHOP was also presented at the 2011 ASCO Annual Meeting.

Data from three pivotal, Phase III studies on the use of Rituxan combined with CHOP or CHOP-like chemotherapy in previously untreated patients with DLBCL was previously submitted to the NCCN panel on March 14, 2011.

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


Rituxan Prescribing Information

Cited References


