June 8, 2010

Submission Request to the NCCN Guidelines Panel for Non-Hodgkin’s Lymphoma

For your consideration, data is available on the use of maintenance Rituxan® (Rituximab) for the treatment of follicular non-Hodgkin’s lymphoma (NHL). The Phase III, international, multicenter, randomized PRIMA study evaluated maintenance Rituxan in patients with previously untreated advanced follicular NHL who responded to initial treatment with Rituxan plus chemotherapy.1,2 The primary endpoint, progression free survival (PFS), was significantly longer in patients who received maintenance Rituxan compared with patients who did not receive maintenance Rituxan (hazard ratio [HR]=0.50; 95% CI: 0.39-0.64). Two-year PFS was 82% (95% CI: 78-86%) in patients who received Rituxan maintenance compared with 66% (95% CI: 61-70%) in patients who did not receive Rituxan maintenance. Grade 3/4 adverse events were reported in 22% of patients who received maintenance Rituxan compared with 16% of patients who did not receive Rituxan maintenance; and included neutropenia (4% vs. 1%, respectively) and infections (4% vs. 1%, respectively).

Long-term outcomes of the Phase III EORTC 20981 trial, which evaluated maintenance Rituxan therapy following induction with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or Rituxan plus CHOP (R-CHOP) in patients with relapsed/resistant follicular NHL, have recently been published.3 With a median follow-up of 6 years, the primary endpoint, PFS, was 3.7 years in patients who received maintenance Rituxan compared with 1.3 years in patients who did not receive maintenance Rituxan (HR=0.55; p<0.001). The 5-year overall survival, a secondary endpoint, was 74% in patients who received maintenance Rituxan and 64% in patients who did not receive maintenance Rituxan, but the difference was not statistically significant (p<0.07). In the Rituxan maintenance arm, Grade 3/4 neutropenia and infection were reported in 11.5% and 9.4% of patients compared with 6.0% and 2.4% in the observation arm, respectively.

In addition, the Phase III ECOG 1496 study (Study 5 in the Rituxan PI), which evaluated the use of Rituxan following induction with CVP chemotherapy has been enclosed for your review.4 Rituxan is not FDA-approved for the use of maintenance following induction with Rituxan plus chemotherapy for the treatment of follicular NHL. Please refer to the enclosed prescribing information for the full FDA-approved indications and safety information.5

The enclosures listed below are included for your review (copyright-paid where applicable). The 2010 ASCO oral presentation on the PRIMA study will be sent in a follow-up communication as soon as copyright permissions have been obtained.

- Rituxan Prescribing Information
Cited References


5. Rituxan Prescribing Information