On behalf of Genentech, I respectfully request the NCCN Non-Hodgkin’s Lymphoma (NHL) Guideline Panel to review the enclosed data for Rituxan® (Rituximab) plus lenalidomide for the treatment of NHL.

Specific Changes: Consider the recently presented data on Rituxan plus lenalidomide for the treatment of NHL for your updating purposes.

FDA Clearance: The FDA has not approved Rituxan plus lenalidomide for the treatment of NHL. Please refer to the enclosed prescribing information (PI) for the full FDA-approved indications and safety information.

Rationale: Results from three Phase II studies evaluating Rituxan plus lenalidomide for the treatment of NHL were recently presented at the 11th International Conference on Malignant Lymphoma (ICML) on June 15-18 in Lugano, Switzerland.1-3  In a Phase II study by Fowler and colleagues, the overall response rate (ORR) was 90% (n=70) for patients with untreated indolent NHL who received Rituxan plus lenalidomide. In a Phase I/II study by Wang and colleagues, patients with relapsed/refractory mantle cell lymphoma who received Rituxan plus lenalidomide had an ORR of 57.8% (n=52). In another Phase I/II study, Nowakowski and colleagues reported an ORR of 100% (n=30) in patients with aggressive B-cell lymphomas who were treated with Rituxan plus lenalidomide. The most frequently reported Grade 3/4 adverse events in the three studies were thrombocytopenia, lymphopenia, neutropenia, febrile neutropenia, fatigue, rash, muscle pain, thrombosis, and dehydration.

Additional data on Rituxan plus lenalidomide for the treatment of NHL has been previously reported.4-13

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

- Rituxan Prescribing Information

Cited References


