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Submitted by:

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NCCN Guidelines Panel: Non-Hodgkin's Lymphoma

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 chlorambucil for the treatment of chronic lymphocytic leukemia (CLL).

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

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

Rationale: Results from two Phase II studies evaluating Rituxan plus chlorambucil in elderly patients with previously untreated CLL were recently presented at the 11th International Conference on Malignant Lymphoma (ICML) on June 15-18 in Lugano, Switzerland and the 2011 American Society of Clinical Oncology (ASCO) Annual Meeting on June 3-7 in Chicago, Illinois.^{1,2} In the two Phase II studies, overall response rates for the first-line treatment of CLL were approximately 80%. In the study by Hillmen and colleagues, median progression-free survival was 23.9 months.¹ Reported adverse events included neutropenia.²

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

- Hillmen P, Gribben JG, Follows GA, et al. Rituximab plus chlorambucil (R-chlorambucil) as first-line treatment for chronic lymphocytic leukaemia (CLL): final analysis of an open-label phase II study. *Ann Oncol* 2011;22(suppl 4):iv123-iv124. ICML Abstract #016
- Mauro FR, Ciolli S, Di Raimondo F, et al. A phase II study of chlorambucil plus rituximab followed by maintenance versus observation in elderly patients with previously untreated chronic lymphocytic leukemia: results of the induction phase. *J Clin Oncol* 2011;29(suppl):abstract 6629.
- Rituxan Prescribing Information

Cited References

1. Hillmen P, Gribben JG, Follows GA, et al. Rituximab plus chlorambucil (R-chlorambucil) as first-line treatment for chronic lymphocytic leukaemia (CLL): final analysis of an open-label phase II study. *Ann Oncol* 2011;22(suppl 4) :iv123-iv124. ICML Abstract #016
2. Mauro FR, Ciolli S, Di Raimondo F, et al. A phase II study of chlorambucil plus rituximab followed by maintenance versus observation in elderly patients with previously untreated chronic lymphocytic leukemia: results of the induction phase. *J Clin Oncol* 2011;29(suppl):abstract 6629.