



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 11<sup>th</sup> 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.<sup>1,2</sup> 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.<sup>1</sup> Reported adverse events included neutropenia.<sup>2</sup>

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.