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Dear Dr Catchpole,

Thank you for your response to the clarification letter on 18 December 2008.

The ERG has a further question to ask as follows;

“In your clarification letter to the ERGs initial questions on your submission, you have included the results of the one-way sensitivity analysis that adjusts for differential mortality rates, and examines the effect of removing the impact of an overall survival advantage in the model between R+FC and FC arms (Table 15 p.22 in Clarification letter). Given that, from the trial evidence it seems difficult to very clearly demonstrate an overall survival advantage between the two arms of the CLL8 trial (eg. p.70 Roche submission : “With an additional 4.8 months of observation time, the difference in OS between treatment arms was not significant”) and secondly, the fact that the use of an aggregated progression state is acknowledge as a potential weakness of the model (Item d p. 156 of Roche submission), it would seem to us that this an area of structural uncertainty in the economic analysis which has not been

fully encompassed in the Probabilistic Sensitivity Analysis (PSA). In view of this, we would request if possible a re-run of the PSA which more fully incorporates this key aspect of structural uncertainty”.

Could you send us your response by the end of 9 January 2009?

Thank you for your cooperation.

Best regards,

Kim Jeong

Health Technology Analyst
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