

23 June 2010

## **Reply to the NICE Appraisal Consultation Document of 'Bortezomib and thalidomide for the first-line treatment of multiple myeloma'**

Response from the MRC Myeloma IX Trial Management Group and Clinical Trials Research Unit, University of Leeds

The Myeloma IX Trial Management Group welcomed the opportunity to submit the results of the MRC Myeloma IX Trial for consideration in this appraisal, and thank NICE and the Assessment Group for respecting the confidential nature of these data.

We were disappointed that only the response data from the Myeloma IX Trial was included in the systematic review, and that the overall survival, progression-free survival, adverse events and health-related quality of life data were considered not eligible for inclusion because of the maintenance randomisation component of the trial.

We note that the additional data we submitted from the small number of patients who were randomised to receive no maintenance therapy, were considered, but not included in the review, as the data were considered too immature and for a small number of patients. There is no mention in the consultation document about the additional modelling data that we submitted which included larger patient numbers (patients excluded from the maintenance randomisation plus patients randomised to receive no maintenance therapy).

Despite these concerns, we support the Committee's recommendation that 'Thalidomide in combination with an alkylating agent and a corticosteroid is recommended as an option for the first-line treatment of multiple myeloma in people for whom high-dose chemotherapy with stem cell transplantation is considered inappropriate.'

We would be delighted to continue to cooperate with NICE in their consideration of the Myeloma IX data and share the results of our further analyses when the guidance is reviewed. The proposed timeline of August 2013 would tie in very well with our next planned analysis.

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**On behalf of the MRC Myeloma IX Trial Management Group**