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Our Ref: GJM/DF0263

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S E N T B Y E M A I L

Reetan Patel
Technology Appraisal Project Manager
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71 High Holborn
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Dear Reetan,

RE: Single Technology Appraisal (STA), Bortezomib Monotherapy for Relapsed Multiple Myeloma Appraisal Consultation Document

Thank you for giving me the opportunity to comment on the revised ACD, Bortezomib Monotherapy for Relapsed Multiple Myeloma.

i) Given the constraints of the Appraisal that insists on the consideration of monotherapy only, I consider that all the relevant evidence has been taken into account, but clearly, as I have stated previously, I think that the response rates with combinations including Velcade will be higher than those with single agent Velcade alone.

ii) I think that the summaries of the clinical and cost effectiveness of Bortezomib and monotherapy are reasonable interpretations of the evidence, are relevant clinically and allow a consideration of the cost effectiveness of the drug. The concept of a VRS (Velcade Rebate Scheme) is a good idea and I consider the summaries of the cost effectiveness presented in the hearing to be an accurate reflection of the clinical use of this drug. In particular, I would like to stress that in my opinion, if the Rebate Scheme is followed, that the majority of patients will benefit and the small minority of patients who may show signs of a response after 4 cycles, is not a significant clinical consideration. In my own clinical practice, I would be unlikely to wish

to consider on going treatment, unless I had seen, what I consider a meaningful clinical response, by this number of cycles.

liii) I consider the provisional recommendations of the Appraisal Committee to be sound and constitute a suitable basis for the preparation of guidance to the NHS. In conversations I have had with the company, they have outlined what sounds like a very 'forgiving strategy' for the use of this Scheme. However, I would like to be sure that the NHS receives firm assertions that the assessment of response will not be punitive, and that over interpretation of paraprotein responses will not be made and used as a way of avoiding a rebate. Similarly, given the wording of the Appraisal, I would like to be reassured that the Rebate Scheme is available for all patients where Bortezomib is used, not only at first relapse. It is also important that the administration underlying the scheme, is functional, and does not impose an excess of work on the pharmacy and clinical staff.

I am sure that all of these issues can easily be addressed, but we do need to have reassurance and commitment from the company to make this happen.

Yours sincerely,

Gareth Morgan, PhD, FRCP, FRCPath
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Section of Haemato-Oncology