National Institute for
Health and Clinical Excellence

04 April 2007

MidCity Place
71 High Holborn
London
WC1V 6NA

Tel: 020 7067 5800
Fax: 020 7067 5801
Email: nice@nice.org.uk
www.nice.org.uk

Dear Ms Chatham,

Health Technology Appraisal
Bortezomib monotherapy for relapsed multiple myeloma

Following the outcome of the Appeal Panel decision sent to you on 26 March 2007, I am writing to you to request confirmation of the position of the Welsh Assembly Government in relation to the 'risk-sharing' arrangements proposed by Janssen-Cilag for the provision of bortezomib, within its licensed indication, for relapsed multiple myeloma, in the NHS in England and Wales.

As you are aware this appraisal is being sent back to the Appraisal Committee, where it will be discussed on 8 May 2007. In order to fully prepare for that meeting we need your response by **17 April 2007** at the latest.

We would appreciate to receive the following details of the risk-sharing arrangement together with your comments in each case:

- the patient group for whom the proposed arrangement is being created – for example, patients who have suffered a first relapse;
- the number of cycles after which response is determined – for example, 3 and/or 4 cycles;
- confirmation that the scheme is designed to be tenable for all NHS organisations in England;
- clarification on the status of the arrangement in terms of the NHS in Wales (we are writing separately to the Welsh Assembly Government, but we are aware that you wish to liaise with them on this matter;
- the duration of the arrangement and, if applicable, details of ant proposed review;
- contact details of the people in the Department of Health who are involved in evaluating the proposal.

Finally, I would like confirm that we are exploring the option of appraising the (unlicensed) use of bortezomib in combination with dexamethasone separately from

our further consideration of its licensed use. Because consideration of the unlicensed use of bortezomib will require a new referral, and in order to not impede the appraisal of the monotherapy (licensed) indication, the committee will not consider off-label use of bortezomib at its meeting on 8 May. The Institute is in contact with consultees on this matter and we hope to present their views on the appropriateness of undertaking a separate appraisal of the use of bortezomib for your consideration within the next month.

I am sending you this letter on the understanding that Simon Reeve from the Department of Health in London will contact you to discuss these requests in further detail. In the meantime, if you wish to discuss the matter further, please contact Meindert Boysen (01612093855 or Meindert.boysen@nice.org.uk).

Please address your response to this letter to Reetan Patel, project manager, on Reetan.patel@nice.org.uk.

Yours sincerely

Carole Longson
Director, Centre for Health Technology Evaluation

CC. Simon Reeve, Andrew Dillon, Meindert Boysen