idm
PHARMA

National Institute for
Health and Clinical Excellence
MidCity Place
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08 December 2008

Re: Single Technology Appraisal – Mifamurtide for the treatment of osteosarcoma.

Dear [redacted]

Please find enclosed our responses to the clinical and cost-effectiveness questions raised by the Evidence Review Group and the NICE technical team, the associated confidentiality checklist and the revised economic models. I trust these responses will satisfactorily address your questions. If you do have any further questions, please do not hesitate to contact me.

I would also like to take this opportunity to inform you of the latest status with our regulatory submission to the EMEA. On November 18, 2008 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMEA) issued a positive opinion, and recommended that a centralised marketing authorisation be granted for mifamurtide (L-MTP-PE), known as MEPACT® in Europe, for the treatment of patients with non-metastatic, resectable osteosarcoma. The CHMP recommendation will be adopted at the next CHMP plenary meeting in December, with the final marketing authorisation expected to be granted by the European Commission within 60 to 90 days thereafter.

As a result of the CHMP positive opinion we have finalised the Summary of Product Characteristics (SPC) and this is also enclosed for your consideration.

Yours sincerely

[redacted]

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