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To Rebecca Pye, Technology Appraisal Project Manager – Committee D

Date 13 November 2012

Concerning **THE ACD ON COLISTIMETHATE SODIUM POWDER AND TOBRAMYCIN POWDER FOR INHALATION FOR THE TREATMENT OF *Pa* LUNG INFECTION IN CF**

Dear Rebecca,

Novartis welcomes the opportunity to comment on the above Appraisal Consultation Document (ACD) and accompanying Evaluation report which were disseminated on 16 October 2012.

Novartis is delighted that the preliminary guidance from the Appraisal Committee outlined in the ACD recommends the use of tobramycin inhalation powder. In issuing this preliminary recommendation, the Appraisal Committee has recognised the added benefits of tobramycin inhalation powder for the treatment of chronic pulmonary infection caused by *Pseudomonas aeruginosa* in people with cystic fibrosis. Futhermore, we are pleased that qualitative parameters have been taken into consideration, primarily around the possibility that patients on dry powder inhalers may be more likely to comply than those on nebulised treatment due to the speed and convenience of drug delivery.

Overall, we found the Appraisal Committee has taken into account all of the relevant evidence and consider, in general, that the summaries of clinical and cost-effectiveness are reasonable interpretations of the evidence. Novartis supports the provisional recommendations as a sound and suitable basis for guidance to the NHS.

Within the Evaluation Report, there are a number of possible points of clarification. However, these comments are unlikely to materially affect the overall conclusions determined by the Appraisal Committee and thus extensive comments have not been put forward.

Once again, we are grateful for the opportunity to comment on the ACD and look forward to continued dialogue with NICE.

Regards,

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