National Institute for Health and Clinical Excellence

29 October 2008

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Dear consultees and commentators,

Health Technology Appraisal Bevacizumab, sorafenib, sunitinib and temsirolimus for the treatment of advanced and/or metastatic renal cell carcinoma

As you know, the Appraisal Committee has held its second meeting to discuss the appraisal of bevacizumab, sorafenib, sunitinib and temsirolimus for the treatment of advanced and/or metastatic renal cell carcinoma.

During consultation on the Assessment Report and Appraisal Consultation Document (ACD), new data for a subgroup of patients was received from the marketing authorisation holder of sunitinib. As a result of these submissions, and the response to the ACD by the marketing authorisation holder of bevacizumab, the Institute has commissioned further critical review of the evidence base.

In accordance with our published process, we must consult on the new evidence and the results of the critical review before convening a final meeting of the Appraisal Committee, which will now take place on 14 January 2009.

I know that you will share my disappointment that the appraisal will need to be extended, but I hope you will agree that it is important that the basis on which the Appraisal Committee will make its recommendations is made available to you before it does so.

We would prefer to receive your comments in electronic format, either by email or on compact or floppy disk, although we can also accept printed documents. Please send your comments to Christopher Feinmann, Technology Appraisal Project Manager, by email to

<u>Christopher.Feinmann@nice.org.uk</u> or by post to the above address. Your comments will need to be received by 5pm on 26 November 2008.

We will place this letter on our web site on Friday 31 October. Until then, the letter should remain confidential. The additional analysis should remain confidential until the Institute puts it into the public domain following the next meeting of the Appraisal Committee.

Yours faithfully

Dr Carole Longson, Director Centre for Health Technology Evaluation

Enclosed:

- Pfizer's submission made in response to the assessment report and the submission made in response to the ACD.
- Roche Products' response to the ACD.
- AG-PenTAG review of Pfizer's original submission and the submission in response to the ACD.
- DSU review of Roche's request for parameter changes.
- Appraisal Committee's preferred assumptions after considering the responses to consultation, the submissions by Pfizer and Roche and the reviews of the manufacturer submissions by DSU and AG-PenTAG.
- DSU report on Pfizer's cost effectiveness model for sunitinib in the subgroup with no systemic post study treatment incorporating the Committee's preferred assumptions.
- AG-PenTAG's report on the cost effectiveness model for sunitinib in the subgroup with no systemic post study treatment, including using Committee's preferred assumptions.