Bayer's response to the Critical Review Report of new analyses arising from the second committee meeting

Thank you for providing Bayer with the opportunity to respond to the Critical Review Report which evaluates the additional data on sunitinib (referred to as the subgroup) and changes in assumptions to the economic analysis of bevacizumab.

Sunitinib

Bayer are pleased to see that the concerns that we had regarding the subgroup data provided by Pfizer have already been recognised by PenTAG, the DSU and the Appraisal Committee. We believe that the preferred assumptions of the Committee are a pragmatic and valid attempt to handle the limitations of the unplanned, retrospective analysis, and provide the best method to estimate the potential effect of either IFN and sunitinib in a one treatment only pathway. We also acknowledge the DSU's comments that their cost-effectiveness estimates for this subgroup are likely to be higher in practice.

Due to the complexity of treating renal cell carcinoma, Bayer believe that it would be inappropriate for the Committee to consider the sunitinib subgroup in isolation to the other treatments under appraisal in the MTA. Bayer are committed to both patients and clinicians having a choice in the management of renal cell carcinoma. As some patients can and do receive treatment post IFN-α in the UK, Bayer propose that in evaluating a sunitinib (with a no subsequent treatment) strategy, it should be compared against not only IFN-α alone, but also possible sequential treatments (.e.g. IFN-α followed by Nexavar).

Although clinical trials are not necessarily set up in this way, and therefore there is difficulty in interpreting the data for such an evaluation, the treatment algorithm is a valid option for both patients and clinicians. Table 1 shows the potential survival and cost outcomes that such an analysis may provide; similar outcomes to sunitinib could be achieved at lower costs.

Table 1: Overview of outcomes (in years) and costs of a single versus sequential treatment practice

Treatment	Outcome (mean, years)	Cost
Sunitinib alone	3.13*	£54,220^
IFN-α alone	2.29** (1.74 years as progression free)	£22,547^
IFN-α followed by Nexavar		
IFN-α component	1.74 progression free years***	£10,789^^
Nexavar component	[redacted]****	[redacted]****
Combined effect	[redacted]	[redacted]

*DSU report that this could be an overestimate as it includes patients who receive subsequent therapies (Table 4, pg 58).
**DSU estimate of IFN-α (Table 4, pg 58).
*** DSU estimate of IFN-α progression free years (Table 4, pg 58)
****New prior cytokine data
^DSU estimate of total costs of sunitinib and IFN-α (no subsequent treatments, including BSC PD costs) (pg. 58)
^^DSU estimate of IFN-α prior to BSC (progressive disease) (pg. 58)

Bevacizumab

In order to improve the transparency of the Committee's decision for each of the products, we fully support Roche's request that the Committee's documents should explicitly state which model and assumptions they base their decisions on, including the rationale for choosing these.

Summary

We ask that the Committee consider the above comments into account when they meet in January 2009. We also ask that the FAD explicitly contains the reasoning behind the Committee's decision, including how disease severity, patient's clinical need and the unique circumstances surrounding end of life treatment contribute to their interpretation of the ICER for each treatment. In doing so, this would aid the transparency and understanding of the NICE decision process for these products, which is of benefit to patients and their families, clinicians, manufacturers, and the general public.