Comments from Novartis Pharmaceuticals UK Ltd. on the Appraisal Consultation Document (ACD) for the Health Technology Appraisal of Bevacizumab, Sorafenib, Sunitinib and Temsirolimus for Renal Cell Carcinoma

Thank you for your invitation to comment on the above ACD and accompanying documents which were released on the 30th July 2008. We are disappointed that the draft recommendations do not support the use of any of the new targeted therapies for the treatment of renal cell carcinoma. In particular, sunitinib confers significant benefits as monotherapy when compared to IFN-α alone in terms of progression free survival (11 months vs 5 months) and tumour response. Sunitinib therefore offers an effective alternative to immunotherapy as first-line treatment for patients with metastatic renal cell carcinoma. If the draft recommendations are adopted, patients will be denied access to clinically effective treatments for an indication where current treatment options are extremely limited and generally not well tolerated.

The "Updated guide to the methods of technology appraisal - June 2008" states that the Appraisal Committee should take into account the degree of clinical need for patients with this disease. We believe that insufficient weight has been given to this aspect of the appraisal. In addition the recently released report, "NICE Citizens Council report *'Quality Adjusted Life Years (QALYs) and the severity of illness'* recommends that severity should be considered in addition to clinical and cost-effectiveness. We therefore urge the Appraisal Committee to re-consider its decision taking into account the severity of the disease and the significant unmet clinical need for metastatic renal cell carcinoma.

In summary, the preliminary recommendations do not constitute a suitable or sound basis on which to develop guidance to the NHS as they do not give due consideration to the factors described above.