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27th August 2008

Dear Chris

Re: Bevacizumab, sorafenib, sunitinib and temsirolimus for renal cell carcinoma – Appraisal Consultation Document

I write on behalf of the National Cancer Research Institute - Renal Cancer Clinical Studies Group, the Royal College of Physicians, the Royal College of Radiologists, the Association of Cancer Physicians and the Joint Collegiate Council for Oncology in response to the above consultation. We would like to make the following joint response under your general headings:

i) There has been no account taken of the data presented at the American Society of Clinical Oncology by Figlin et al. earlier this year (available at asco.org) where it is clear from the post-hoc subgroup analysis of patients in the Sunitinib vs Interferon trial that the absolute survival in the Interferon arm is enhanced by the high proportion of patients receiving active second line treatments.

ii) The PENTAG QALY analysis is flawed because the group used the data from the bevacizumab trial to model progression with IFN alone; the median survival of the IFN alone group in that trial is far greater that from trials in the pre-TKI era. Using the data from Figlin et al. (ASCO 2008), and a consensus survival estimate from historical controls (either from other trials or from published prognostic models), the overall survival advantage for patients having sunitinib first line is in the order of 9 months. Perhaps the best and most robust data on IFN survival is from the MRC RE04 study (Gore et al. J. Clin. Oncol (ASCO Proceedings) 26,15S Abstract 5039) where median overall survival was 18.7months; this compares with the 26.4 months for sunitinib from the Figlin data. We respectfully ask that the QALY analysis is redone using appropriate comparative data and with expert oncology input. Would it not now be possible to take into account proposals submitted by manufacturers relating to drug acquisitions costs?

iii) Whilst we understand the constraints under which NICE appraises health technologies we consider the provisional recommendations unsound (see above) and inequitable (see below), and as such does not constitute a suitable basis for guidance to the NHS.

iv) Renal carcinoma is one of the less common cancers and, as such, must not be discriminated against. There is no other suitable treatment for the majority of patients with advanced/metastatic disease; Interferon is simply not appropriate for these patients. The new treatments under appraisal offer major and evidence-based clinical benefits. They may be more costly but this is first-line treatment and the actual costs to the NHS are small compared with the multiple NICE approved and expensive treatment options available to other more common cancers, such as breast and colorectal carcinoma. It is a shame that appropriate patients with renal carcinoma are to be denied effective treatments which are readily available to similar patients throughout Europe and America.

I trust these comments will be of use and hope that you will take them into consideration.

Yours sincerely

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