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14 December 2010

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By email to: Kate Moore (<u>TACommD@nice.org.uk</u>)

Dear Appraisal Committee

Single technology appraisal (STA) Vinflunine for the treatment of transitional cell carcinoma of the urothelial tract

Thank you for the invitation to comment on the appraisal consultation document (ACD) on vinflunine for the treatment of transitional cell carcinoma of the urothelial tract. The ACD concludes that vinflunine is not recommended for use as second-line chemotherapy in bladder cancer – on the basis of a lack of a clear statistically significant survival benefit over 3 months and a predicted cost per QALY of £120,000.

As a group our main concern is that there are numerous references in the document to 'alternative' second-line chemotherapy treatments used in the UK. However, because the main registration study was against best supportive care, these treatments are neither defined nor considered in the economic model. The committee acknowledges that this is the first agent with randomised controlled trial data in this setting yet accepts that it is common practice to offer second-line chemotherapy with agents that are unproven, unlicensed in this setting and have not been through any NICE appraisal themselves. When calculating the cost effectiveness of vinflunine, although it may seem reasonable to compare with best supportive care (BSC) as in the trial, in reality these patients are often given unproven chemotherapy which is likely to entail significant cost over that of BSC.

The lack of a proven and approved second-line chemotherapy has led to diverse practice within the uro-oncology community. Patients with metastatic bladder cancer are disadvantaged by the lack of a second line treatment option. Study 302 is the first trial to show a survival benefit and we feel that vinflunine should be available for this relatively small group of patients.

With kind regards

On behalf of Action on Bladder Cancer