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14 December 2010

National Institute for Health & Clinical Excellence Level 1A, City Tower Piccadilly Plaza Manchester M1 4BD (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

We are pleased to comment on the appraisal consultation document (ACD) on vinflunine for the treatment of transitional cell carcinoma of the urothelial tract. The ACD states that vinflunine is not recommended for the indication – on the basis of a lack of a clear statistically significant survival benefit and a predicted cost per QALY of £120,000.

It is a concern that there's frequent mention of 'alternative' second-line chemotherapy treatments used in the UK, but because the main registration study was against best supportive care, these treatments are neither defined nor considered in the economic model.

An additional issue is that although second-line treatments are currently given in the UK, they are off-licence treatments. Vinflunine therefore is the only drug with a randomised controlled trial and licensed indication in this setting which was emphasised at the NICE appraisal.

With the current financial climate, there is likely to be pressure to only use "licensed" drugs and so as vinflunine is licensed for this indication, despite the fact that it seems no better or worse than many of the other drugs used second line, it would at least be giveable on the basis of a drug licensed in this setting whereas purchasers may stop us using the other agents we may use currently.

Yours sincerely

On behalf of the British Uro-oncology Group

BUG Executive Committee: Dr Amit Bahl, Dr Jim Barber, Dr Alison Birtle, Dr Johann de Bono, Dr Steve Harland, Dr Catherine Heath (Treasurer), Dr Robert Huddart (Education Secretary), Mr Roger Kockelbergh, Dr John Logue, Prof Malcolm Mason, Dr Rhona McMenemin, Dr Heather Payne (Chair), Dr Simon Russell (Secretary)

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