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17th January 2010

Dear Dr Longson

Re: Final ACD and Evaluation Report and information on economic model for the appriasal of Lapatinib and trastuzumab - first line (with an aromatase inhibitor)MTA

I write on behalf of the NCRI/RCP/RCR/ACP/JCCO with relation to this Appraisal Consultation Document (ACD) consultation. We are grateful for the opportunity to respond and would like to make the following comments.

• Has all of the relevant evidence been taken into account?

Yes, within the scope of the appraisal all relevant evidence has been considered. In particular the three RCT's that are directly relevant to the appraisal have been analysed in detail.

• Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?

We continue to be concerned regarding the substantial differences in the estimated cost effectiveness of trastuzumab-anastrozole and lapatinib-letrozole arrived at by the Assessment Group. Letrozole and anastrozole have no clinically detectable difference in efficacy and whist there is only limited data comparing trastuzumab and lapatinib, it seems unlikely that there is a major difference between these drugs. Therefore intuitively the 2 drug-combinations being evaluated seem likely to have similar efficacy but it seems a radically different cost-effectiveness.

• Are the provisional recommendations sound and a suitable basis for guidance to the NHS?

Subject to the cost-effectiveness analysis being considered reasonable, then yes.

• Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of gender, race, disability, age, sexual orientation, religion or belief?

No



• Are there any equality-related issues that need special consideration and are not covered in the appraisal consultation document?"

The principal beneficiaries of lapatinib or trastuzumab in combination with endocrine therapy are likely to be older and less fit patients for whom chemotherapy is a particularly unattractive option. This appraisal leaves the option of trastuzumab in combination with chemotherapy available to all patients. However, the considerations that would have prompted clinicians to recommend endocrine therapy in preference to chemotherapy, combined with lapatinib or trastuzumab to some patients with ER-positive HER2-positive patients are likely to result in lower (less effective) doses of chemotherapy being administered to these patients if the option of HER2-targetted therapy in combination with an aromatase inhibitor is not available. Older less-fit patients are therefore likely to be disadvantaged by the recommendations.

Yours sincerely