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Dr Carole Longson
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National Institute for Health and Clinical Excellence
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17th February 2010

Dear Dr Longson

Re: NSCLC - Gefitinib Appraisal Consultation Document

I write on behalf of the NCRI/RCP/RCR/ACP/JCCO with relation to this ACD consultation. We are grateful for the opportunity to respond and would like to make the following comments. Our thanks go to our clinical expert nominee, Professor Mike Lind for coordinating the response.

- Page 15 - 3.24 Cisplatin and Vinorelbine are not commonly used in the U.K. for the treatment of advanced or metastatic lung cancer.

- Page 16 - 3.28; The statement about blinding is not strictly accurate. Evaluation of CT scans etc was blinded within the treating centre but it is true there was no independent review of scans.

- Page 17 - 3.29 There is as yet no evidence of an interaction between EGFR mutation status and chemotherapy sensitivity. If one looks at the EGFR M-ve patients in the IPASS study who received chemotherapy and compares it with the patients who had wild type chemotherapy the median progression free survival of the 2 groups are very similar.

- Page 24 - 4.5 the identification of progressing patients was blinded

- Page 26 - 4.9 there is a major problem with the inclusion of cisplatin/pemetrexed in the mixed treatment group and indeed of any other survival data derived from non-Asian sources because in the IPASS study the majority of patients were female and in the Scagliotti, the majority of patients were male. Sex is known to be an important determinant of survival in NSCLC with women surviving longer.

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Economic Model

The major criticism of the economic model is that no account has been taken of the effect of EGFR mutation testing and first line use of gefitinib will have on second line receptor tyrosine kinase inhibitor use. It will almost certainly fall very substantially resulting in large cost savings

Yours sincerely

Registrar