16th November 2011

NHS
National Institute for Health and Clinical Excellence

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Dear [redacted],

Re: Single Technology Appraisal – Erlotinib for the first line treatment of EGFR-TK mutation positive NSCLC

The Evidence Review Group (LRiG) and the technical team at NICE have now had an opportunity to examine the submission received on the 10th October from Roche. The issues raised by the ERG at the teleconference on 3rd November will be addressed in more detail in their report. The ERG and the NICE technical team would like further clarification relating to the clinical and cost effectiveness data.

Both the ERG and the technical team at NICE will be addressing these issues in their reports.

We request you to provide a written response to this letter to the Institute by **17:00, 23rd November**. Two versions of this written response should be submitted; one with academic/commercial in confidence information clearly marked and one from which this information is removed.

Please underline all confidential information, and separately highlight information that is submitted under 'commercial in confidence' in turquoise, and all information submitted under 'academic in confidence' in yellow.

If you present data that is not already referenced in the main body of your submission and that data is seen to be academic/commercial in confidence information, please complete the attached checklist for in confidence information.

Please do not 'embed' documents (i.e. PDFs, spreadsheets) within your response as this may result in your information being displaced or unreadable. Any supporting documents should be emailed to us separately as attachments, or sent on a CD.

If you have any further queries on the technical issues raised in this letter then please contact Bernice Dillon – Technical Lead (bernice.dillon@nice.org.uk). Any procedural questions should be addressed to Kate Moore – Project Manager (kate.moore@nice.org.uk) in the first instance.

Yours sincerely

Helen Knight
Associate Director – Appraisals
Centre for Health Technology Evaluation

Encl. checklist for in confidence information

Section A: Clarification on effectiveness data

Section 2.4 – Issues relating to clinical pathway of care

A1. **Priority Request:** Please clarify, and if possible state the source of, the stated second-line treatment options for the patients who currently receive first-line gefitinib.

Section 5.3 – Issues relating to methodology of relevant RCTs

A2. **Priority Request:** Please provide copies of the protocols and clinical study reports for the two primary studies (EURTAC and OPTIMAL).

Section 5.7 – Indirect and mixed treatment comparisons

A3. **Priority Request:** Please provide the rationale for including only the third generation doublet chemotherapies in the evidence network and excluding pemetrexed in combination with cisplatin or carboplatin.

Section B: Clarification on cost-effectiveness data

Section 6.2 – De novo analysis

A4. **Priority Request:** Please provide the rationale for not considering trial overall survival results in the de novo economic model. What are the assumptions regarding the relationship between pre-progression survival and overall survival used in the economic model? Please provide a scenario analysis based on the overall survival results from the trials.