Dear Dr George

RE: Gefitinib for the treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC)

Thank you for giving AstraZeneca the opportunity to clarify the situation regarding the anomaly the Evidence Review Group (ERG) detected in the revised economic model, developed in response to the Appraisal Committee’s request for further information.

The root cause of the anomaly is a typographical error in the gefitinib EGFR M+ progression-free survival (PFS) Kaplan Meier (KM) data that was included in the background worksheets of the revised economic model.

The AstraZeneca statistician who worked on the issues relating to model selection and fit had identified and corrected this error. The statistical analyses and models presented in the response to the Appraisal Committee meeting are therefore correct and based on the right PFS KM curve data (see page 5 Figure 2).

It is regrettable that, due to an oversight and time pressures, this error was not also corrected in the PFS background worksheet that was supplied with the revised economic model. However, the Appraisal Committee should note the PFS KM data played no part in the cost-effectiveness calculations.

A copy of the SAS PFS output for the EGFR mutation positive treatment arms of IPASS has been included as an Appendix to this letter. To correct the gefitinib EGFR M+ PFS data in the model a value of 1 should be inserted between cells F69 and F70 in the “Eqns PFS” worksheet and a value of 0.037 should be inserted at the end of the data column in cell F91. The effect of the missing value was to shift the gefitinib PFS KM data to the left by 30 days. This error contributed to the reduction in the PFS advantage for gefitinib reported by the ERG.

You will note that the mean PFS for gefitinib EGFR mutation positive of 10.22 months (310.9 days) estimated using the revised economic model is consistent with the mean of 9.83 months (299.0 days) reported in the SAS KM PFS output (Appendix).

AstraZeneca would like to apologise to NICE, the Appraisal Committee and the ERG for the confusion and additional work this typographical error has caused.

It is unfortunate that time constraints limited the opportunity for the ERG to corroborate the gefitinib PFS KM data in the revised economic model before the additional analyses were conducted and presented to the Appraisal Committee. This could have been done by either contacting AstraZeneca directly, reviewing the PFS
KM curves in the NEJM IPASS publication or comparing the spline models fitted to these data to those fitted to the PFS data in the original ERG report.

I look forward to contacting you on Monday to discuss the way forward.

Yours faithfully
APPENDIX

IRESSA, IPASS study
SAS output for progression-free survival for the gefitinib EGFR M+ subgroup

The LIFETEST Procedure
Stratum 2: TRTRAND = Gefitinib
Product-Limit Survival Estimates

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## The LIFETEST Procedure

### Stratum 2: TRTRAND = Gefitinib

Product-Limit Survival Estimates

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The LIFETEST Procedure

Stratum 2: TRTRAND = Gefitinib

Product-Limit Survival Estimates

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<th>Survival</th>
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NOTE: The marked survival times are censored observations.

Summary Statistics for Time Variable PROGDAYS

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<th>Percent</th>
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Mean Survival Time: 298.981
Standard Error: 15.516

NOTE: The mean survival time and its standard error were underestimated because the largest observation was censored and the estimation was restricted to the largest event time.