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Worldwide Pharmaceutical Operations

27th June 2008 Direct Line: [redacted]

Dr Carole Longson
Director
Centre for Health Technology Evaluation
National Institue for Health and Clinical Excellence
MidCity Place
71 High Holborn
London WC1V 6NA

Dear Dr Longson

Health Technology Appraisal
Bevacizumab, sorafenib, sunitinib and temsirolimus for renal cell carcinoma

In the original submission for this Appraisal Pfizer gave an undertaking to provide final results from the A6181034 study as and when they became available, alongside revised cost-effectiveness analyses.

An early version of the final results was communicated to NICE on 2nd May 2008. A more complete version of the results has subsequently been presented at the American Society of Clinical Oncology meeting during the week commencing 30th May 2008.

In line with our commitment to provide all results as the become available please find attached a copy of the presentation from the meeting. Pfizer believes that these updated results are critical to gaining an understanding of the clinical value of sunitinib in practice as they now provide an analysis of Overall Survival (OS) for patients who did not receive any post study treatment for their metastatic Renal Cell Carcinoma (mRCC). The feedback from UK oncologists after the presentation was that this was the more informative of the analyses and the most useful for guiding clinical practice. Pfizer is also aware that there is work ongoing in using Marginal Structural Modelling to handle time dependent confounders such as this[i,ii].

Please also find attached the revised cost-effectiveness analyses that were committed to be sent to you. For completeness and transparency these cover the full Intention To Treat analysis, the analysis with cross-overs censored and the analysis that excludes patients who received post study treatments for their mRCC. **Please note that if all of these results had been available at the**

time of the original submission, Pfizer would have used the latter (even though post hoc) analysis as the base case for sunitinib based on relevance for guiding clinical practice.

Pfizer is aware of the limitations of the final results as presented at the ASCO meeting and is willing to provide further data as and when requested by NICE or the Assessment Group.

Please do not hesitate to contact me if you have any queries relating to the above or the attachments.

Yours sincerely

[redacted]

Enc.

[i] Hernán MA, Brumback B, Robins JM. Marginal Structural Models to Estimate the Causal Effect of Zidovudine on the Survival of HIV-Positive Men. Epidemiology 2000;11(5):561-570.

[ii] Wang, Y., Hong, S., and **Zhang, M.** (2008) Using marginal structural model to adjust for post-study treatment. (In Preparation) and: http://statgen.ncsu.edu/icsa2007/talks/Session%205A%20MSM%20for%20ICSA%202007%20Yanping%20Wang.ppt