[redacted]

21 February 2013

RE: Bevacizumab in combination with gemcitabine and carboplatin for treating recurrent advanced ovarian cancer

[redacted]

Thank you for the opportunity to comment on the ACD for the above technology appraisal. We are disappointed that the Committee has decided not to recommend bevacizumab for the treatment of women with platinum sensitive recurrent ovarian cancer. We are pleased that the Committee has recognised the difficulty associated with calculating the overall survival benefit of adding bevacizumab to gemcitabine and carboplatin in these patients, due to increasing use of anti-angiogenesis therapies after progression in the key clinical study (OCEANS). We remind the Committee that the effect of this crossover in the placebo controlled arm of OCEANS is likely to confound estimates of any survival benefit and result in inflated estimates of cost-effectiveness. Furthermore, the absence of an external dataset for survival of these patients precludes attempts to explore what would have happened in the control arm in the absence of bevacizumab. However, we do not believe any such adjustment would materially affect the decision reached by the Committee.

In addition, we have identified 2 factual inaccuracies in the report:

- Section 3.5 (p8): The hazard ratio for the third interim OS analysis is incorrectly stated as "relative to bevacizumab" – this should be changed to "relative to placebo"
- Section 3.8 (p9): The wording of the first paragraph suggests that our search identified 4 RCTs which directly compare bevacizumab + carboplatin + gemcitabine with the other comparators listed in the scope – this is incorrect, no other RCTs were identified.

If any clarification or further analyses would aid the Committee in their deliberations we would be more than happy to provide it.

Yours Sincerely,

[redacted]

Roche Products Limited

6 Falcon Way
Shire Park
Welwyn Garden City
Hertfordshire, AL7 1TW
Registered in England No.100674

Health Economics and Strategic Pricing
Bldg/Room 02-N36

Tel: +44 (0)1707 365772
Fax: +44 (0)1707 384527
Email: lee.moore@roche.com