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Healthcare Management Director

Monday 26th June 2006

Emily Marschke
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BY E-MAIL

Dear Emily,

HEALTH TECHNOLOGY APPRAISAL – Bevacizumab and cetuximab for advanced colorectal cancer

Thank you for the opportunity to comment on the Appraisal Consultation Document (ACD) for the above technology appraisal.

We have a number of important points of feedback which are set out below in the three response sections required by the Committee.

1. "Whether you consider that all of the relevant evidence has been taken into account"

Roche believes that all of the relevant evidence has been taken into account during the appraisal.

However, as might be expected for a new and innovative drug such as bevacizumab, the evidence base is rapidly being added to and new data are constantly emerging. This was demonstrated most recently, for example, by the large number of research presentations at the recent ASCO meeting which took place earlier in June. Across the current and upcoming indications for bevacizumab presently being studied, a total of 74 abstracts were presented at ASCO of which 23 were in colorectal cancer and five in other GI related tumours.

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As a result of the rapidly developing clinical and cost effectiveness evidence base both in metastatic colorectal cancer and in the other upcoming indications for bevacizumab, Roche would like to request that bevacizumab be considered for an early re-review in one years time via the NICE technology appraisal programme.

2. "Whether you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate"

Roche strongly concurs with the conclusions drawn by the Committee that bevacizumab offers significant clinical benefits for patients with metastatic colorectal cancer when added to first-line fluoropyrimidine + / - irinotecan containing chemotherapy regimens.

3. "Whether you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS"

Roche very much welcomed the consideration by the Appraisal Committee of the Avastin Registry Programme (ARP) as we had requested and which was submitted alongside the economic modelling undertaken for this particular appraisal.

However, since the Appraisal Consultation Document was issued, we have now received updated information regarding earlier timelines for the launch of additional licensed indications for bevacizumab which are now expected in 2007 for metastatic breast cancer (high dose indication); non-small cell lung cancer (high and low dose indications); renal cell carcinoma (high dose indication); and for combination treatment with oxaliplatin and fluoridopyrimidine-based regimens for metastatic colorectal cancer (low dose indication). Each of these indications is at various stages of progression through the NICE topic selection process.

In the light of these timelines, Roche considers it important to re-evaluate the overall position of bevacizumab's future use in the NHS with a view to being able to satisfactorily address the UK issues of cost effectiveness on a broader basis.

Commercial-in-Confidence (BEGINS)

We regret to inform you that we are therefore now unable to proceed with the Avastin Registry Programme as part of the current technology appraisal of bevacizumab at this point in time and would ask that the Committee's further deliberations to produce the Final Appraisal Determination (FAD) are made without it.

We are taking this step because it has been identified that there are some basic issues of concern with the proposal, particularly around the long-term implementation and longevity of the programme in relation to the launch of the additional licensed indications.

The SMC also recognised such issues in its recent review and subsequent rejection of bevacizumab for metastatic colorectal cancer and we believe that these issues now need to be satisfactorily resolved on a national basis before progressing further.

In the light of the above position and in order to avoid confusion within the NHS when guidance is issued, we would like to request that the Final Appraisal Determination (FAD) developed by the Committee does not make reference to the Avastin Registry Programme (ARP) as presently described in the ACD in paragraphs 4.2.5 and 4.3.6.

Roche wishes to assure the Appraisal Committee that we remain fully committed to finding a workable solution to allowing bevacizumab to be made available to NHS patients at the earliest opportunity.

Commercial-in-Confidence (ENDS)

The new indications referred to above for breast, lung and renal cancer are already at various stages of the horizon scanning process for NICE topic referral and we remain supportive of them being brought forward in due course for appraisal as part of the new Single Technology Appraisal (STA) process at the earliest possible opportunity.

Please do not hesitate to contact me if you require any further clarification or explanation of our feedback.

Yours sincerely,