Abbott's response to the Appraisal Consultation Document of abatacept for the treatment of rheumatoid arthritis after the failure of conventional disease-modifying anti-rheumatic drugs

Abbott welcomes the opportunity to comment on the Appraisal Consultation Document (ACD) prepared by the Committee for the appraisal of abatacept for the treatment of rheumatoid arthritis (RA) in DMARD failure patients. Abbott's comments are set out under section headings containing the questions NICE asks consultees to comment on for the ACD.

1. Do you consider that all of the relevant evidence has been taken into account?

Abbott is unaware of any relevant evidence that the Committee has not taken into account

2. Do 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?

Section 4.9 of the ACD states that "*The Committee was aware that in practice these people may receive rituximab*".

Although this paragraph also goes on to state that "*the Committee acknowledged that in strict accordance with the marketing authorisation and the NICE recommendations for rituximab, people must have disease that has shown an inadequate response, or be intolerant to, TNF inhibitors to receive rituximab*", Abbott is concerned that this statement may be seen to encourage off-licence use of rituximab in a population in which the European Medicines Agency (EMEA) has expressed concerns around the risk benefit profile.

In 2010 the EMEA considered the use of rituximab in patients who have not previously received an anti-TNF. Following a full review of the evidence, the CHMP concluded that "*the benefit-risk balance for rituximab in MTX-naïve patients (1st line treatment) and in MTX-IR patients (2nd line treatment) was not favourable and that the therapeutic efficacy has not been properly and sufficiently demonstrated*."(p53 EPAR)[1]

The EPAR reports that "*a major concern was raised as long-term safety data in the sought indications were lacking, and the consequences of long-term consequences of long-term B-cell suppression in the RA population were unclear".* They also noted that "*the efficacy data to support the 1st and 2nd line treatment was insufficient*", and "*the effect of rituximab on prevention of radiographic progression seems less than reported for TNF-alpha blockers*".

The manufacturer subsequently withdrew their application for a licence extension, and have informed NICE that they "will not be seeking a license for this particular indication at the present time"[2].

3. Do 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?

Abbott can understand why the Committee has made its preliminary recommendations for abatacept.

4. Are there any equality related issues that may need special consideration?

Abbott is not aware of any equity related issues that may need special consideration in the preliminary recommendations.

References

[1] European Medicines Agency Assessment Report for Mabthera (rituximab). http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Assessment_Report_-_Variation/human/000165/WC500099488.pdf Accessed 12 April 2011

[2] National Institute for Health and Clinical Excellence http://guidance.nice.org.uk/TA/Wave24/0 Accessed 12 April 2011