Together we will beat cancer

CANCER RESEARCH UK

Cancer Research UK response to NICE Appraisal Consultation Document assessing abiraterone for castration-resistant metastatic prostate cancer previously treated with a docetaxel-containing regimen

Declaration of interest

Cancer Research UK was involved in the initial stages of the development of abiraterone and receives royalties from its sale, which we reinvest in research.

Response to consultation

Cancer Research UK welcomes the opportunity to respond to this initial NICE decision. We recognise that NICE has a difficult job to do and by and large we believe it performs it well; it is not often that we question NICE's decisions. However, on this occasion we consider it our duty to do so. We endorse the NCRI Prostate Cancer Clinical Studies Group's response, which is appended.

We are calling on NICE to reassess abiraterone using End of Life criteria, as the AWMSG was able to do. We note that the initial decision stated that these criteria were not used on the basis that the population that would be eligible to receive abiraterone is not considered 'small'. However, discussions with clinicians have confirmed that they believe the population to be fewer than 5,000 men. We would be interested to see more details of the expert commissioner's advice which led to the figures submitted by Janssen being dismissed as underestimates.

We are in the unusual position that many men are already receiving abiraterone on the Cancer Drugs Fund and it will also be routinely funded in Wales unless a final negative decision from NICE is forthcoming. We know that these men and their clinicians value the extra months of life and enhanced quality of life the drug offers them. Indeed, we have received a number of testimonies to this effect from patients in letters and via social media since the initial decision.

We recognise that the initial decision stated that even if End of Life criteria had been applied, the drug would still not have been approved, however, we are also calling on Janssen to lower the drug's price to a level that would be acceptable for routine use on the NHS.

23 February 2012

Appendix 1
NCRI Prostate Cancer Clinical Studies Group response

Feedback on NICE ACD for Abiraterone

Has all of the relevant evidence been taken into account?

Yes

Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?

There is agreement that is an effective, safe and well tolerated drug that prolongs life and improves quality of life. There is disagreement between the company and the ERG on the precise details of cost effectiveness modeling and assignation of health Utility Values, but this is beyond the scope of our professional expertise. We have concerns that the ERG assumes that men who may be offered treatment with Abiraterone have a low Utility Value, but it we would like to point out that these men generally have few co-morbidities otherwise they would not have been fit enough for the previous docetaxel and reduced functionality is generally due solely to their cancer. As a group, they are fitter than average for their years in our judgement. Abiraterone clearly leads to an improvement in quality of life and pain scores in men with symptoms and delays onset of pain in asymptomatic men.

The steep fall off in the trial was a real event and we think it may represent the ability of the trialists to keep to the protocol and maintain patients on drug/placebo even though they were progressing clinically and biochemically. At 3 months radiological confirmation of disease progression would have resulted in a large number of patients coming off drug (placebo) at the same time point. We think that this means patients are modelled to stay in the pre-progression state for longer in the prednisolone arm than happened in the trial and thus underestimated the real benefit of Abiraterone. We believe that Abiraterone is an innovative drug as it is the first in class of a biologically targeted agent aimed at inhibiting a key pathway in androgen biosynthesis. Studies with this agent have shown that prostate cancers, far from becoming 'hormone-resistant', remain androgen –driven and indeed are androgen super-sensitive, in that they synthesise and respond to low levels of their own androgen. Abiraterone is the drug that has led to a redefinition of the disease states in prostate cancer (though our Consumer representatives have consistently reminded us that patients do not like the term 'castrate-resistant').

Another economic consequence of this appraisal would be that UK participation in future international cancer trials is significantly reduced, as NHS standard practice is significantly different from the rest of the international community. The patient representatives on the CSG feel particularly strongly about this, as an important issue additional to the concerns about the availability of the drug to suitable patients. For patients whose treatment would have otherwise been funded in a trials setting, the full costs will now fall on the NHS. This deserves to be modeled.

Are the provisional recommendations sound and a suitable basis for guidance to the NHS?

No

We believe that this drug should be considered under the 'end of life' considerations at it meets <u>all</u> of the requirements, specifically that previous agreed end of life diseases have included a patient population of over 5000, and the total population of patients with prostate cancer who are fit

enough to receive docetaxel falls well short of the approximately 10-12,000 who die of prostate cancer per year in the UK – in some regions it may be as few as 20%.

We accept that there may remain some doubt about the ICER. However, we believe that NICE and Janssen should consider innovative approaches to ensuring patient access to Abiraterone while the uncertainties re ICER are addressed.

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of gender, race, disability, age, sexual orientation, religion or belief?

No

Are there any equality -related issues that need special consideration and are not covered in the appraisal consultation document?

No