

Joint submission on bortezomib for multiple myeloma ACD.

Leukaemia Research has joined IMF (UK) and Leukaemia Care in submitting a joint response to the STA ACD on bortezomib for multiple myeloma.

We would wish to make the following additional points.

The Leukaemia Research myeloma cytogenetics database located at Salisbury and headed by Dr Fiona Ross is a unique resource. The database is closely integrated with the current myeloma trials in a way which offers unprecedented opportunities to correlate biological features of the disease with responses to therapy. If the effect of the ACD (translated unaltered to an FAD) were to be reduction of entry into trials, or even patchy entry, this would greatly compromise this prospect. The joint submission has proposed that bortezomib should be approved for use at first relapse with detailed follow-up studies – the existence of the myeloma cytogenetics database will greatly enhance the effectiveness of such a follow-up program.

Leukaemia Research would refer the appraisal committee to the precedent set in the transition from ACD to FAD for imatinib for treatment of chronic myeloid leukaemia. It is appreciated that, in the case of drugs with novel modes of action, it is particularly difficult to achieve effective comparison with existing treatments. We are concerned that this does not act to the disadvantage of patients and would urge the committee to, once again, take the path which will encourage development of novel therapies. This is particularly vital in instances such as myeloma, where there is a general agreement that existing therapies are far from optimal.

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