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Dr Mark Chakravarty

Lead Non-Executive Director for Appeals & Vice Chairman National Institute for Health and Care Excellence

2 October 2023

Dear Mark,

Re: Withdrawal of draft final guidance for belantamab mafodotin for treating relapsed or refractory multiple myeloma after 4 or more therapies [ID2701]

The Centre for Health Technology Evaluation is aware that the [European Medicines](https://www.ema.europa.eu/en/news/ema-recommends-non-renewal-authorisation-multiple-myeloma-medicine-blenrep) [Agency’s Committee for Medicinal Products for Human Use (CHMP) has](https://www.ema.europa.eu/en/news/ema-recommends-non-renewal-authorisation-multiple-myeloma-medicine-blenrep) [recommended not renewing the conditional marketing authorisation for belantamab](https://www.ema.europa.eu/en/news/ema-recommends-non-renewal-authorisation-multiple-myeloma-medicine-blenrep) [mafodotin](https://www.ema.europa.eu/en/news/ema-recommends-non-renewal-authorisation-multiple-myeloma-medicine-blenrep) after reviewing results from the DREAMM-3 study, which failed to show that patients treated with belantamab mafodotin lived longer without their disease getting worse than those treated with pomalidomide and low-dose dexamethasone. This phase 3, open-label, randomised study compared belantamab mafodotin with pomalidomide and low-dose dexamethasone in 325 patients with relapsed/refractory multiple myeloma. The primary endpoint agreed as part of the specific obligation was superiority in investigator-assessed progression-free survival (PFS). The study found no statistically significant difference in PFS between the two groups (HR 1.03; 95% confidence interval: 0.72, 1.47).

The Medicines and Healthcare products Regulatory Agency (MHRA), the regulator of medicines in the UK, will make the decision on whether the licence is not renewed within the UK. We would like to advise you that we are withdrawing the draft final guidance and pausing the appraisal until NICE has received the MHRA’s decision as we are not aware of any evidence to suggest the MHRA will not follow the CHMP recommendation. We understand that the ongoing appeal process will be cancelled as a result of this action.

Kind regards,

**Dr Jacoline Bouvy** *(she/her)*

Programme Director – Medicines Evaluation Centre for Health Technology Evaluation

