Sent by e-mail only: XXXXXXXXXXXXXXXXXXXXXXX

XXXXXXXXXXXXXX,

XXXXXXXXXXXXXXXXXXX, Myeloma UK

1 September 2023

Dear XXXXXXXX

**Re: Final Draft Guidance (FDG) - belantamab mafodotin for treating relapsed or refractory multiple myeloma after 4 or more prior therapies [ID2701]**

Thank you for your appeal of 8 August 2023 and your email of 29 August confirming you would submit no response to my initial scrutiny views. This is my final decision on initial scrutiny.

I confirm that, for the reasons set out in my initial scrutiny letter, the valid appeal points are:

* 2.1: The Appraisal Committee's conclusions:
1. that the GSK naive comparison using Named Patient Program (NPP) data (which favoured belantamab compared with pomalidomide plus dexamethasone for all outcomes) "lacked validity and added further uncertainty";
2. that the randomised subgroup data from DREAMM-3 was preferable to the non-randomised evidence presented by the company; and
3. that it had not been presented with sufficient evidence to confirm that belantamab is more clinically effective than pomalidomide plus dexamethasone at a population level

are individually and collectively unreasonable.

* 2.2 (arising from your original appeal point 1(a).2): The Committee's conclusion that "additional data collection would be unlikely to resolve the uncertainty around the efficacy of belantamab compared with the relevant comparators for this evaluation" was unreasonable in light of the evidence;

NICE shares the valid appeal grounds of each appellant with the other appellants to assist with preparation for the hearing.

NICE will be in contact with you regarding the administration of the appeal, which will be held orally.

Yours sincerely

Dr Mark Chakravarty

Lead Non-Executive Director for Appeals & Vice Chairman

National Institute for Health and Care Excellence