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Sent by e-mail only:

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Melanoma Focus

28 September 2023

Dear

**Re: Final Appraisal Document — Tebentafusp for treating advanced uveal melanoma [ID1441]**

I write to follow up my letter of 7 September 2023 setting out my initial scrutiny views. I note that Melanoma Focus did not reply to that letter. This is my final decision on initial scrutiny.

***Ground 2: the recommendation is unreasonable in the light of the evidence submitted to NICE***

# Appeal point 2.1: The committee’s statement (para 3.11) that “The clinical experts suggested that uveal melanoma is an aggressive disease and that there is no expectation that tebentafusp would be curative. So it is not expected that the overall survival curve would plateau” is flawed, misinterprets expert opinion and makes an inappropriate conclusion to justify use of parametric curves

I confirm my decision to refer this appeal point to the Appeal Panel.

# Appeal point 2.2: The committee’s statement (para 3.11) that “The committee considered that standard parametric curves should be the starting point for modelling and could be used for this treatment” is illogical and does not adequately reflect that non-parametric modelling has been established by NICE committees as the most appropriate (and now standard) methodology in immunotherapy appraisals. The committee and the ERG have failed to distinguish the most appropriate methodology for an immunotherapeutic despite precedent

I confirm my decision to refer this appeal point to the Appeal Panel. Conclusion

Therefore the valid appeal points are:

* 2.1: The committee’s statement (para 3.11) that “The clinical experts suggested that uveal melanoma is an aggressive disease and that there is no expectation that tebentafusp would be curative. So it is not expected that the overall survival curve would plateau” is flawed, misinterprets expert opinion and makes an inappropriate conclusion to justify use of parametric curves.



* 2.2: The committee’s statement (para 3.11) that “The committee considered that standard parametric curves should be the starting point for modelling and could be used for this treatment” is illogical and does not adequately reflect that non-parametric modelling has been established by NICE committees as the most appropriate (and now standard) methodology in immunotherapy appraisals. The committee and the ERG have failed to distinguish the most appropriate methodology for an immunotherapeutic despite precedent.

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

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