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Sent by e-mail only:

FAO

Melanoma Focus 7 September 2023

Dear

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

Thank you for your letter of 22 August 2023, lodging an appeal against the above Final Appraisal Document (FAD).

Introduction

The Institute's appeal procedures provide for an initial scrutiny of points that an appellant wishes to raise, to provide an initial view on whether they are within the permitted grounds of appeal ("valid") and are at least arguable. The permitted grounds of appeal are:

* 1(a) NICE has failed to act fairly, or
* 1(b) NICE has exceeded powers;
* (2) the recommendation is unreasonable in the light of the evidence submitted to NICE.

This letter sets out my initial view of the points of appeal you have raised: principally whether they fall within any of the grounds of appeal, or whether further clarification is required of any point. Only if I am satisfied that your points contain the necessary information, are arguable, and fall within any one of the grounds will your appeal be referred to the Appeal Panel.

You have the opportunity to comment on this letter in order to elaborate on or clarify any of the points raised before I will make my final decision as to whether each appeal point should be referred on to the Appeal Panel.

Initial View

I assess each of your points in turn. I have renumbered these points to comply with NICE's appeal process guide (section 4.6).

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

# 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 am minded 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 am minded to refer this appeal point to the Appeal Panel. Conclusion

The above sets out above my initial views on all of your appeal points.

In respect of your points which I am not minded to refer on you are entitled to submit further clarification and/or evidence to me within the next 10 working days, and I will then give a final decision on the points to put before an appeal panel. For the points I am already content to refer on, an oral appeal will be held which will be held remotely.

Once I have made my final decision, and where there is more than one appellant, each appellant will receive the valid appeal points of the other appellants and their redacted appeal letter. This is to enable appellants to avoid duplication at the hearing where there are overlapping appeal points. If the appeal letter and/or responses to scrutiny contain confidential information please ensure you have provided a version with this information redacted by 28 September 2023.

Ordinarily appeals are conducted on the basis of the appellants’ written appeal letters, and the material generated during the appraisal process. Use of additional written material is discouraged, and the panel cannot receive any new evidence. If, exceptionally, you feel there is written material that will not be before the panel that you would wish to rely on you must let the NICE Appeal team know by return of letter, indicating what the material is, why it is desirable to submit it, and when it will be available, by no later than 29 September 2023. Please note that the appeal panel cannot accept papers that are tabled late or ad hoc, as this affects the preparation of the panel and other parties for the appeal.

Yours sincerely

Dr Mark Chakravarty

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