

*United Against Ocular Melanoma Cancers*

31st August 2023

Dr Mark Chakravarty

Lead non-executive director for appeals

National Institute for Health and Care Excellence 2nd Floor, 2 Redman Place

London, E20 1JQ

Dear Dr Chakravarty,

# Appeal against the decision not to recommend Tebentafusp for treating advanced (unresectable or metastatic) uveal melanoma [ID1441]

OcuMel UK are the only UK patient organisation solely dedicated to supporting people affected by Ocular Melanoma. We are appealing the decision to not recommend Tebentafusp for treating advanced (unresectable or metastatic) uveal melanoma on the following grounds:

* Ground 1) NICE determined that Tebentafusp would be unsuitable for the Cancer Drugs Fund based on the likely impact of the severity modifier at exiting the CDF rather than on the end-of-life modifier that applied to Tebentafusp at the time of appraisal.
* Ground 2) the recommendation is unreasonable in the light of the evidence submitted on the impact of Tebentafusp on the Quality of Life of patients with advanced uveal melanoma and the costs associated with this condition.

Ground 1: In making the assessment that preceded the recommendation, NICE has:

1. failed to act fairly or
2. exceeded its powers

# Ground 1. NICE determined that Tebentafusp would be unsuitable for the Cancer Drugs Fund based on the likely impact of the severity modifier at exiting the CDF rather than on the end-of-life modifier that applied to Tebentafusp at the time of appraisal.

NICE may have exceeded its powers in considering the impact of the new severity modifier on the treatment if it were exiting the CDF in a number of years rather than on the end-of-life criteria applicable to the treatment at the time of the appraisal. This meant there was no opportunity to pursue an agreement to enter the Cancer Drugs Fund, depriving patients of an effective treatment and preventing additional data collection to address any clinical uncertainties. This was an unfair decision as it treated Tebentafusp differently to other cancer treatments, particularly those for rare cancers, which had the opportunity to enter the Cancer Drugs Fund regardless of their likelihood of meeting the new severity modifier requirements upon exiting the fund.

Whilst we recognise that the Grounds of Appeal do not allow for appeals against the scope of the appraisal, we would like to note that it is unclear to us why this appraisal was not undertaken through the NICE Highly Specialised Technologies programme due to the rarity of the condition (only 650 patients have ocular melanoma). Of these around 50% will develop metastases and of these, 50 % would be eligible for treatment with Tebentafusp. If Tebentafusp had been considered through the HST route there is a strong chance it would now be reimbursed for patients in England and Wales.

**Ground 2: The recommendation is unreasonable in the light of the evidence submitted to about the Quality of Life of people affected by advanced uveal melanoma and the costs associated with this condition which should have been taken regarding the end­ of-life criteria and not the requirements of the new severity modifier.**

The evidence required focussed on meeting the requirements for the end-of-life care modifier. This was well demonstrated but overlooked by NICE when considering whether Tebentafusp would be suitable for consideration by the Cancer Drugs Fund. In addition, inadequate consideration was given to the evidence on the maintenance of a good Quality of Life until shortly before death, something that the NICE Committee may have limited familiarity with given the nature of progression in many cancers. Similarly cost data is lower than might be expected in some advanced cancers and the committee did not give this due consideration. There appears to have been an underestimation of the Qol of patients and an over estimation of the costs associated with advanced uveal melanoma which resulted in Tebentafusp not being recommended for consideration in the Cancer Drugs Fund.

OcuMel UK worked hard to ensure effective participation in the appraisal but feel the rarity of this cancer means people have been disadvantaged as there is little data on the quality of life for people with advanced disease. Consideration to the Cancer Drugs Fund could have allowed an opportunity to collect data that will be lost unless patients have access to this drug as the lack of other treatment options has been well documented.

We feel this review could have been more successful if there was recognised data on the impact of advanced ocular melanoma and the potential impact of treatment. This would have allowed for greater understanding of the nature of advanced melanoma and the Health Related Quality of Life of affected individuals, notably that they may experience few symptoms until before dying due to the way in which liver metastases progress.

We look forward to hearing from you soon on each of these points.

Yours sincerely,

