­Sent by email to: XXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXX

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British Association of Dermatologists

25 March 2021

Dear XXXX XXXXXX

**Re: Final Appraisal Document –** **Mogamulizumab for previously treated mycosis fungoides and Sézary syndrome [ID1405]**

Thank you for your letter received on 18 March 2021, lodging the British Association of Dermatologists (BAD)’s 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 confirm that they are at least arguably within the permitted grounds of appeal ("valid"). 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 and arguably 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 understand from your letter that BAD supports the appeal made by the UK Cutaneous Lymphoma Group (UKCLG). My initial response to UKCLG’s appeal is enclosed for your reference, but I would ask that any response to that letter comes directly from UKCLG as the appellant.

In addition, I note that BAD appears to put forward a single, additional appeal point as follows:

*“the BAD would like to appeal against the decision not to recommend mogamulizumab for previously treated mycosis fungoides and Sézary syndrome, and our appeal should be based on ground two –. there is compelling evidence for efficacy and with no other treatment options for certain patients with life-threatening disease”.* In particular, you state: “*The MAVORIC trial is the largest randomised controlled trial (RCT) in cutaneous T-cell lymphoma (CTCL), which is a rare T-cell lymphoma with poor outcomes for advanced disease and a lack of effective treatment options due to a high level of chemo-resistance. The trial included a high proportion of patients with the leukaemic stage of disease, i.e. Sézary syndrome, which is associated with a very poor prognosis and for which there are no consistently effective treatment options. The trial represents the largest series of patients with Sézary syndrome enrolled in an RCT and shows a clear benefit for patients receiving mogamulizumab, which is reflected in the clinical uptake on the compassionate access program in the UK following approval by the EMA. This also reflects the lack of approved options such as brentuximab for CD30-positive CTCL, as Sézary syndrome is invariably CD30-negative. Specifically, mogamulizumab provides people with the very rare Sézary syndrome with the opportunity of long-term remission following reduced-intensity stem cell transplantation.”*

I understand this point to be that the FAD is unreasonable because of the Committee’s conclusions regarding the MAVORIC trial.

It is important to appreciate that an appeal committee cannot redo the work of the committee on the merits, and intervenes only if the committee’s judgements are unreasonable, and it is possible for reasonable people to differ on issues without either person’s conclusion being unreasonable.

I am not presently minded to refer this point to the appeal panel, as it is not in my view arguable from the information you have provided that the Committee’s assessment of the MAVORIC trial evidence was unreasonable.

You are entitled to submit further clarification and/or evidence to me within the next 10 working days, no later than **Monday 12 April 2021**, and I will then give a final decision on the points to put before an appeal panel. If your appeal point was not referred forward this would not prevent you attending the appeal jointly with UKCLG and supporting their arguments.

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 **Tuesday 20 April 2021**.

Yours sincerely

Tim Irish

Vice Chair

National Institute for Health and Care Excellence