Sent by e-mail only: XXXXXXXXXXXXXX

FAO XXXXXXXXXXXXX

Incyte Biosciences UK Ltd

Thursday 8 August 2024

Dear XXXXXXXX

**Re:** **Final Draft Guidance For Ruxolitinib Cream For Treating Non-Segmental Vitiligo In People 12 Years And Over [ID 3998]**

Thank you for your letter of 1 August 2024, lodging an appeal against the above Final Draft Guidance (FDG).

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. Before I do so, I note your introductory comment that "Incyte is fully committed to co-operation with NICE, including further commercial negotiation, in order to achieve a favourable outcome to this appraisal". I am pleased that Incyte is committed to co-operating with NICE but wish to make clear that it is not for NICE to enter into any commercial negotiation with companies. That is a matter for Incyte and NHS England, which may be taken into account by NICE in its appraisals (if negotiation is successful) but is outside of our remit when carrying out technology appraisals.

***Ground 1(a): In making the assessment that preceded the recommendation, NICE has failed to act fairly***

**Appeal point 1(a).1: NICE’s refusal to include technical engagement in the appraisal despite requests by Incyte, was procedurally unfair**

I am minded to refer this appeal point to the Appeal Panel.

**Appeal point 1(a).2: A third meeting of the Appraisal Committee should have been scheduled in view of the issues which were unresolved at the second meeting and in order adequately to consider data requested by the Committee and submitted by Incyte in response to the draft guidance**

I am minded to refer this appeal point to the Appeal Panel specifically as regards whether sufficient time was permitted at the second appraisal committee meeting ("ACM2") for consideration of the new data provided by Incyte and, if not, it was unfair not to schedule a third committee meeting ("ACM3"). I note that it is not uncommon for an FDG to raise new points not addressed in the consultation document which is a natural consequence of NICE's iterative decision-making process, and that in itself does not indicate arguable unfairness. I anticipate the panel will wish to explore whether adequate opportunity was given for fair consideration of the issues at the two committee meetings and what a third meeting might have achieved. This point is procedural and does not relate to the reasonableness of the committee's conclusions on any issue.

**Appeal point 1(a).3: The Committee’s conclusion that the indirect treatment comparison of Ruxolitinib cream and phototherapy was not robust due to variation in baseline characteristics between studies is unexplained**

I am minded to refer this appeal point to the Appeal Panel as regards whether adequate reasons were provided in the FDG.

**Appeal point 1(a).4:** **The Committee has failed to give adequate consideration to its duty under the Equality Act 2010**

I do not regard this as a valid appeal point under ground 1(a) (procedural unfairness) because I consider the Committee did take into account relevant evidence (see para 3.20 of the FDG). It appears to me that your primary argument is that the Committee’s conclusion that “there were no equality issues relevant to the recommendations” fails to reflect the available data. I consider this a valid appeal point under ground 2 and am minded to refer it on that basis.

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

**Appeal point 2.1: The Committee has disregarded real world evidence and expert evidence for the purposes of decision-making on dosing**

I am minded to refer this appeal point to the Appeal Panel as regards whether the committee's conclusion at paragraph 3.12 of the FDG (that "it was most appropriate to use the dosing estimate from TruE-V that excluded the outliers rather than the estimate calculated using the lognormal distribution") was reasonable in light of the evidence put to the Committee. For the avoidance of doubt I consider it clear that the Committee was aware of all of the evidence and its limitations (see discussion at para 3.12) and there is no arguable point under ground 1(a) that it "disregarded", in the sense of failing entirely, to consider relevant information. Rather the panel will need to explore the weight afforded to the real world and expert evidence and whether the Committee's conclusion was reasonable in light of that evidence.

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. Responses must deal only with requested clarifications, or arguments or comments about the lead non-executive director for appeals' initial view that an appeal point is not valid. 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 30 August 2024.

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 20 September 2024. 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

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Dr Mark Chakravarty

Lead Non-Executive Director for Appeals & Vice Chairman

National Institute for Health and Care Excellence