21 August 2024

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**Appeal against the Final Draft Guidance (FDG) for ruxolitinib cream for treating non-segmental vitiligo in people 12 years and over [ID 3998]**

Thank you for your letter dated 8 August 2024, in which you provide your initial views in relation to the admissibility of the points of appeal set out in Incyte’s letter of appeal of 1 August 2024.

We welcome your conclusion that our appeal points may proceed to an oral hearing and, as suggested in your letter, we provide further detail to elaborate or clarify those appeal points where your conclusion that they should proceed is qualified in some way.

Incyte notes your initial view in relation to appeal points 1a.1, 1a.3 and 2.1 and provides no further submissions in relation to those points at this stage.

**Appeal point 1(a).2:**

Thank you for confirming that you are minded to refer this appeal point to the Appeal Panel. You say that your initial view specifically covers 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").

However, important aspects of this point of appeal also cover the fact that NICE’s procedures provide that one factor which should prompt consultation and that Incyte (and other stakeholders) had no opportunity to respond to the EAG’s critique of Incyte’s data. These matters would argue strongly in favour of a further period of consultation and a third committee meeting in this case. They are not however addressed in your letter, and we are concerned to confirm that they form part of appeal point 1a.2 which will be referred to the Appeal Panel.

Finally, you say that it is not uncommon for an FDG to raise new points not addressed in the consultation document, as part of NICE's iterative decision-making process. You say that this in itself does not indicate arguable unfairness. In this case however, as explained in our appeal letter, issues accepted by the Committee at ACM1, were then challenged at ACM2, with no opportunity for Incyte to respond to them. While we accept that recommendations may change between Draft Guidance and the FDG without there being any need for further consultation, the extent of such changes and the fact that they resulted from reversals in the Committee’s position means that further consultation was required.

In summary, it is the cumulative effect of all the matters raised at point 1a.2 of our appeal that means that failure to schedule a third meeting of the Committee was unfair and all of such elements should be permitted to proceed to an Appeal Panel.

**Appeal point 1(a).4:**

You express the initial view that this point of appeal should proceed under Ground 2, rather than Ground 1a, on the basis that you consider the Committee did take into account relevant evidence on equalities issues as set out at paragraph 3.20 of the FDG and you construe Incyte’s case to be that the Committee’s conclusion that “there were no equality issues relevant to the recommendations” fails to reflect the available data.

However, while the FDG lists various equality issues at paragraph 3.20, it provides no explanation of how these have been taken into account or reasons to justify its conclusion that “there were no equality issues relevant to the recommendations”. In circumstances where transparency is a key requirement of procedural fairness, the lack of reasoning to explain how the Committee has complied with its legal obligations under the Equalities Act 2010 represents a procedural deficiency, which we believe is properly advanced within the context of Ground 1a.

For completeness, it is Incyte’s view that if the Committee’s reasoning had demonstrated complete disregard for important evidence on equalities issues or showed that the Committee had reached conclusions that did not reflect the available evidence, this would represent a failure of the Committee to comply with its duties under the 2010 Act, which would be an appeal properly advanced under Ground 1b.

We hope that this letter addresses the concerns raised in your letter of 8 August 2023. If any aspect of our appeal remains unclear, we will be pleased to provide further assistance. Alternatively, we look forward to receiving your final scrutiny letter.

Yours sincerely,

Incyte Biosciences UK Ltd