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Director – Value, Access and Pricing UK & Ireland

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Sent by e-mail only: xxxxxxxxxxxxxxx

12 October 2022

Dear xxxxxxx

**Re: Final Appraisal Document — Tafasitamab with Lenalidomide for treating relapsed or refractory diffuse large B-cell lymphoma [ID3795]**

Thank you for your letter of 10 October 2022. This is my final decision on initial scrutiny.

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

**Appeal point 1a.1: NICE has failed to act fairly because “The Committee has not taken loss of lenalidomide exclusivity and the associated impact on lenalidomide costs into account in the context of this appraisal”**

Having considered your further arguments, I agree that this is a valid appeal point. As I understand the additional arguments made in your letter of 10 October 2022, they can be summarised as follows:

1. By the time of the second Committee meeting on 2 August 2022, bids would have been received by CMU in the ongoing tender exercise for lenalidomide and therefore by that point the CMU knew what the eventual price payable would be. Alternatively (per your point (5), that tender exercise had already concluded and so the price had been determined. Either way, Incyte’s position is that NICE should have requested that information and taken it into account. Alternatively, NICE should have postponed the Committee meeting until such time as the information was available and could be taken into account.
2. By the date of issue of the FAD on 1 September 2022, the tender had concluded and lenalidomide was being supplied in accordance with nationally agreed prices set by that tender exercise. Your position is that NICE should have requested that information and taken it into account.

I reach my view on the basis that it would be arguably unfair for the Committee to have reached its conclusion on the basis of the list price if the new nationally agreed price was available to it by either 2 August 2022 or 1 September 2022.

For the avoidance of doubt, I do not agree that there would be arguable unfairness if the new nationally agreed price was only available after the issuance of the FAD. In that scenario, the complaint as I understand it would be based on an argument that the Committee should have postponed its process until such point as the nationally agreed price became available. That would introduce a requirement on the Committee that does not feature in the Methods Guide or the Guide to the Processes of Technology Appraisal and which would result in considerable uncertainty in the timing of the appraisal process and potentially significant opportunity cost in delaying other appraisals scheduled for consideration by that Committee. I do not think that a failure to delay in those circumstances could have been arguably unfair. Section 2.4.24 of the Guide to the Processes of Technology Appraisal does provide the opportunity for the Company to request a delay to the appraisal after formal referral. This offers the opportunity on a case-by-case basis to agree a delay in the event that the Company expect new and material information only to be available after the programme timeline.

**Appeal point 1a.2: NICE has failed to act fairly because “the Committee’s conclusions regarding the cost-effectiveness of tafasitamab and lenalidomide lack transparency and are therefore unfair”**

Having considered the additional arguments made in your letter of 10 October 2022, I agree that this is a valid appeal point.

I reach this view on the basis of my understanding that Incyte was not privy to the ERG’s base case, and therefore it is arguable that the ICER range provided by the Committee was insufficiently transparent because Incyte did not know the upper boundary of that range. I would expect the Appeal Panel to focus on whether or not the range provided by the Committee was unfair for that reason.

I would add that I do not share your view that *“Incyte is… entitled to be informed how far NICE believes it would have to move on price before a positive recommendation would be given”.* This would go well beyond the requirement set out in the Methods Guide and which you fairly quote in your letter, to *“…publish an ICER range that informs the recommendation(s), after taking into account the exact level of the discount provided in the commercial arrangement for the comparator”.* (emphasis added)

**Appeal point 1a.3: NICE has failed to act fairly because “The Committee’s decision that tafasitamab and lenalidomide should not be recommended for use through the Cancer Drugs Fund in view of the lack of comparative evidence is procedurally unfair”**

I confirm my view that this is a valid appeal point for consideration under ground 2, for the reasons set out in my letter of 26 September 2022.

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

**Appeal point 2.1: The recommendation is unreasonable because “the Committee’s conclusion that patients eligible for treatment with tafasitamab and lenalidomide do not meet the end of life criteria does not reflect the balance of the available evidence”**

I confirm my view that this is a valid appeal point.

**Appeal point 2.2: The recommendation is unreasonable because “the Committee’s conclusion that the company’s base case ICERs were not plausible because the model survival outputs were not consistent with TA 649 disregards the evidence generated since that appraisal”**

I remain of the view that the Committee’s conclusion on this point was not arguably unreasonable, and therefore this appeal point should not proceed to an oral hearing.

This is because I do not accept that *“the Committee’s only reason for criticising Incyte’s base case ICERs… is the lack of consistency with TA 649”.* As noted in my letter of 26 September 2022, the Committee sets out extensive additional consideration and reasoning in section 3.6 of the FAD, making it clear that additional factors were taken into account in reaching its conclusion on this point.

**Appeal point 2.3: The recommendation is unreasonable because “the Committee’s conclusion that the evidence presented did not demonstrate that tafasitamab is innovative is inconsistent with the Promising Innovative Medicine (PIM) designation by MHRA and the Committee’s own conclusions elsewhere in the FAD”**

I remain of the view that the Committee’s conclusion on this point was not arguably unreasonable, and therefore this appeal point should not proceed to an oral hearing.

In reaching this view, I took account of the fact that the Committee expressly noted the positive impact of treatment administered in an outpatient setting, and that people with the condition have a high unmet need for effective treatments with manageable side effects. The Committee also considered the clinical experts’ assessment of how innovative the technology is, identified the correct test that it needed to apply, and having done so, reached its expert view on whether or not that test was met. For the reasons set out in my initial scrutiny letter, that conclusion is not inconsistent with either the Promising Innovative Medicine designation by MHRA or the Committee’s own conclusions elsewhere in the FAD. I appreciate that Incyte may not agree with the Committee’s conclusion, but that is not sufficient to make it arguably unreasonable.

Yours sincerely

Dr Mark Chakravarty

Lead Non-Executive Director for Appeals & Vice Chairman

National Institute for Health and Care Excellence