­Sent by email to: [x](mailto:christopher.kiff@bms.com)xxxxxxxxxxxxxxxxxxxxxxx

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Bristol-Myers Squibb Pharmaceuticals Limited

Uxbridge Business Park

Sanderson Road

Uxbridge, Middlesex

UB8 1DH

8 October 2020

Dear XX XXXXX

**Final Appraisal Document - Nivolumab for previously treated locally advanced or metastatic non-squamous non-small-cell (NSQ NSCLC) lung cancer [ID1572] (CDF review TA848)**

Thank you for your letter of 1 October 2020, lodging Bristol Myers Squibb’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

You have (rightly) related your concerns with this appraisal to the Institute’s appeal points, with the result that there are a number of appeal points all addressing the same underlying alleged error, namely that the Institute should have conducted this review in light of all the available evidence and not only in light of the original evidence and the evidence collected through use in the CDF. Rather than respond to each appeal point individually I will give my view globally under each ground of appeal:

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

**Ground 1(a).1 — NICE has unjustifiably departed from the 2015 and 2019 Scopes and the Methods Guide**

**Ground 1(a).2 — The premise that the 2017 CDF recommendation limits the scope of the 2019 CDF review has no procedural basis, misinterprets the CDF process and falls short of BMS’ legitimate expectations (three subpoints)**

**Ground 1(a).3 — NICE’s approach in ID1572 has infringed fundamental public law principles (four subpoints)**

Subject to my query below I agree these are all valid appeal points.

***Ground 1(b) — NICE has exceeded its powers***

**Ground 1(b).1 — NICE has breached its legal obligations under human rights and equalities laws (four subpoints)**

Subject to my query below I agree this is a valid appeal point.

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

**Ground 2.1 — The FAD is based on fundamentally incorrect assumptions, errors of fact and an unreasonable review of the evidence submitted**

**Ground 2.2 — The Appraisal Committee’s reasons for refusing to consider the totality of BMS’ evidence are perverse**

**Ground 2.3 — The recommendation makes an unreasonable and arbitrary distinction based on a patient’s PD-L1 expression states, which is a limited and imperfect biomarker in this population**

Subject to my query below I agree these are all valid appeal points.

My query is this: it is not appropriate at the initial scrutiny stage to resolve any question of fact, but it is appropriate for me to understand what is being alleged. This appeal turns on what was in fact submitted to NICE and when. Could you clarify for me if you did submit all the data from CheckMate 017 (SQ) & 057 (NSQ) re PD-L1 positive patients, PD-L1 <1% patients, and unquantifiable PD-L1 patients, and if so when?

As to the appeal hearing itself I noted above, most if not all of your individual appeal points are consequences of NICE failing to consider all of the currently available evidence, if it was obliged to do so and if there was relevant and appropriate evidence that it did not in fact consider. I appreciate that in answering the fundamental question of principle of whether NICE is obliged to consider all available evidence during a CDF review it is likely to be necessary to refer to individual grounds of appeal. It will no doubt be argued that it is the fact that, say, the recommendation would be unreasonable if it was considered in the light of all the available evidence that demonstrates that all of the available evidence must be considered. Clearly we have to look for some structure and rules to answer the question whether NICE must have considered this material or not, and the appeal grounds may provide part of that structure, particularly as they relate to the processes that must be followed by NICE.

However, and subject to how the appeal panel chairman wishes to conduct the hearing, I would suggest as guidance that it would be helpful for you and for the committee alike to focus primarily on the single underlying question of whether new material that is available but is not generated through CDF use has to be considered. It seems to me this is a case where NICE is alleged to have made one overarching error, (which may have the consequence of multiple appeal points) rather than multiple independent errors. I suggest it will be helpful to maintain attention on the alleged overarching error rather than the consequences (save to the extent that the consequences prove that the approach taken is indeed in error).

Please would you answer the question I have posed above within the next 10 working days, by no later than **22 October 2020**. If your answer is these data were submitted then this initial scrutiny letter will also stand as the final scrutiny letter. If there is some other answer I will consider your points and I will then give a final decision on the points to put before an appeal panel. An oral appeal will be held, although under current circumstances this is likely to be held remotely in part or in whole.

Many thanks

Yours sincerely

Tim Irish

Vice Chair

National Institute for Health and Care Excellence