



Pfizer Limited
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9th June 2023

Dear Mark,

Thank you for your Initial Scrutiny Letter, dated 19th May 2023. We are grateful for your review of our Appeal letter.

While Pfizer believes certain aspects of this appraisal and the conclusions set out in the Final Appraisal Document (FAD) are procedurally unfair and/or unreasonable, after careful consideration of your scrutiny letter, we are writing to inform you of our decision to withdraw our appeal.

This decision is due to NICE's refusal to accept the model structure we proposed (even though this reflects that relied upon by NICE in most other appraisals of oncology medicines) and its assumption that future data from the CROWN trial will not be generalisable to the UK population. We disagree with these conclusions and would have wished to work with the Committee to obtain a positive outcome to this appraisal in the interests of patients. However, following your Scrutiny Letter and the exclusion of our appeal on those points, we do not see a commercially viable path forward for lorlatinib in first-line lung cancer at this time. We have therefore decided to withdraw our Appeal and await further data to strengthen our position that our modelling approach and the data from CROWN are plausible, generalisable, and compelling. We recognise that you were minded to refer Appeal Ground 1.1, to the Appeal Panel. The potential benefit of lorlatinib in preventing CNS progression has a significant impact on the ICER and plausible cost-effectiveness and we believe it is important that the Appraisal Committee explains how this has been taken into account in any future consideration of the product.

In summary, although first-line lorlatinib use is recommended in Scotland, based on the conclusions set out in the FAD, we do not believe it is currently feasible to pursue a recommendation for use in England. When further data become available, we will reconsider the position and hope to achieve a more favourable assessment by the Appraisal Committee at that stage. Thank you for considering our appeal.

Yours sincerely,

[Redacted]

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