National Institute for Health and Care Excellence

Single Technology Appraisal (STA)

Afatinib for treating locally advanced or metastatic squamous non-small-cell lung cancer after platinum-based chemotherapy [ID969]

Response to consultee and commentator comments on the draft remit and draft scope (pre-referral)

Please note: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Comment 1: the draft remit

Section	Consultee/ Commentator	Comments [sic]	Action
Appropriateness	Boehringer Ingelheim	We continue to propose that this topic should not proceed to a NICE technology appraisal. • The justification, in brief, is: • LUX-Lung 8 was phase III trial of afatinib (BIBW 2992) versus erlotinib for the treatment of squamous cell lung cancer after at least one prior platinum-based chemotherapy, demonstrating that: “The significant improvements in progression-free survival and overall survival with afatinib compared with erlotinib, along with a manageable safety profile and the convenience of oral administration suggest that afatinib could be an additional option for the treatment of patients with squamous cell carcinoma of the lung”. • These results are not limited to any mutation status in patients with NSCLC of squamous histology. We’ve also heard in advisory boards and in clinical practices that clinicians in the UK also do not consider the EGFR mutation status to be of relevance in patients with	Thank you for your comments.

Section	Consultee/ Commentator	Comments [sic]	Action
		squamous cell carcinoma of the lung. • NICE TA374, published on the 16 December 2015, recommends erlotinib in the post-chemotherapy setting only in the EGFR mutation positive (EGFR m+) NSCLC patients and a set of very specific circumstances around this. • NICE TA310, published on the 23 April 2014, already allows for afatinib's usage in the post-chemotherapy setting in EGFR m+ NSCLC patients. We have fed this in on the 11 December 2015 in the consultation period accompanying the "Company consideration letter with HSRIC briefing", and again via email on the 22 January 2016 in reply to questions from NICE while developing this draft scope. Given the justification above, and in consideration of the considerable public resources and time involved in a NICE technology appraisal, we continue to propose that this topic should not proceed beyond this draft-scope consultation phase to a NICE technology appraisal.	
	British Thoracic Society	The British Thoracic Society supports the proposed appraisal. There is an urgent need more treatment options for patients with advanced lung cancer given the very poor prognosis.	Thank you for your comments.
Wording	Boehringer Ingelheim	NA, in light of our comments in the 'appropriateness' section of comments on the draft remit.	Thank you for your response.
Timing Issues	Boehringer Ingelheim	NA, in light of our comments in the 'appropriateness' section of comments on the draft remit.	Thank you for your response.
Additional	Boehringer	NA, in light of our comments in the 'appropriateness' section of comments on	Thank you for your

Section	Consultee/ Commentator	Comments [sic]	Action
comments on the draft remit	Ingelheim	the draft remit.	response.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Boehringer Ingelheim	NA, in light of our comments in the 'appropriateness' section of comments on the draft remit.	Thank you for your response.
The technology/ intervention	Boehringer Ingelheim	NA, in light of our comments in the 'appropriateness' section of comments on the draft remit.	Thank you for your response.
Population	Boehringer Ingelheim	NA, in light of our comments in the 'appropriateness' section of comments on the draft remit.	Thank you for your response.
Comparators	Boehringer Ingelheim	NA, in light of our comments in the 'appropriateness' section of comments on the draft remit.	Thank you for your response.
Outcomes	Boehringer Ingelheim	NA, in light of our comments in the 'appropriateness' section of comments on the draft remit.	Thank you for your response.
Economic analysis	Boehringer Ingelheim	NA, in light of our comments in the 'appropriateness' section of comments on the draft remit.	Thank you for your response.
Equality and Diversity	Boehringer Ingelheim	NA, in light of our comments in the 'appropriateness' section of comments on the draft remit.	Thank you for your response.

Section	Consultee/ Commentator	Comments [sic]	Action
Other considerations	Boehringer Ingelheim	NA, in light of our comments in the 'appropriateness' section of comments on the draft remit.	Thank you for your response.
Innovation	Boehringer Ingelheim	NA, in light of our comments in the 'appropriateness' section of comments on the draft remit.	Thank you for your response.
Questions for consultation	Boehringer Ingelheim	NA, in light of our comments in the 'appropriateness' section of comments on the draft remit.	Thank you for your response.
Additional comments on the draft scope	Boehringer Ingelheim	NA, in light of our comments in the 'appropriateness' section of comments on the draft remit.	Thank you for your response.

The following consultees/commentators indicated that they had no comments on the draft remit and/or the draft scope

Department of Health
Roche