

Technology Appraisal Committee Meeting (Committee D)

Minutes: Confirmed

Date and Time: Thursday 26 May 2016 10:15 – 17:00

Venue: National Institute for Health and Care Excellence
Level 1A, City Tower
Piccadilly Plaza
Manchester
M1 4BT

Present:	1. Professor Gary McVeigh, Chair 2. Dr Lindsay Smith, Vice Chair 3. Professor David Bowen 4. Dr Matthew Bradley 5. Dr Ian Campbell 6. Dr Ian Davidson 7. Professor Simon Dixon 8. Dr Alexander Dyker 9. Professor Paula Ghaneh 10. Professor John Henderson 11. Mr Malcolm Oswald 12. Dr Paula Parvulescu 13. Dr Mohit Sharma	Present for all notes Present for all notes
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In attendance:

Meindert Boysen	Programme Director, National Institute for Health and Care Excellence	Present for all notes 01 to 34
Professor David Bowen	Investigational Physician University Hospital Leeds	Present for all notes 01 to 34
Dr Matthew Bradley	Astrazeneca	Present for notes 26 to 34
Dr Ian Campbell	Consultant Physician Llandough Hospital	Present for all notes 01 to 34
Mrs Karen Clayton	Patient Expert National Lung Cancer Forum for Nurses	Present for notes 01 to 15
Erny Claxton	Global Reimbursement & Managed Markets, United Therapeutics	Present for notes 26 to 34
Dr Ian Davidson	PAM	Present for all notes 01 to 34
Richard Diaz	Technical Analyst,	Present for notes 26 to 34

	National Institute for Health and Care Excellence	
Professor Simon Dixon	Health Economist	Present for all notes 01 to 34
Sally Doss	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 01 to 15
Matthew Dyer	Health Economics Manager, AstraZeneca	Present for notes 01 to 15
Dr Alexander Dyker	Clinical Pharmacologist Newcastle Hospitals Trust	Present for all notes 01 to 34
Dr Jesme Fox	Patient Expert Roy Castle Lung Cancer Foundation	Present for notes 01 to 15
Serban Ghiorghiu	Global Clinical Lead Lung Cancer, AstraZeneca	Present for notes 01 to 15
Janette Greenhalgh	ERG representative, LRI _G	Present for notes 01 to 15
Professor Paula Ghaneh	Honorary Consultant Surgeon	Present for all notes 01 to 34
Dr Christian Griffiths	University of Liverpool Technical Analyst, National Institute for Health and Care Excellence	Present for notes 01 to 15
Dr Caroline Hall	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 16 to 25
Professor John Henderson	Paediatrician	Present for all notes 01 to 34
Urpo Kiiskinen	University of Bristol Health Economics Advisor, Eli Lilly	Present for notes 16 to 25
Helen Knight	Associate Director, National Institute for Health and Care Excellence	Present for all notes 01 to 34
James Mahon	ERG representative, LRI _G	Present for notes 01 to 15
Fiona Maxwell	Medical Advisor, Eli Lilly	Present for notes 16 to 25
Kate Moore	Project Manager, National Institute for Health and Care Excellence	Present for all notes 01 to 34
Dr Thomas Newsom-	Clinical Expert	Present for notes 1-15

Davis	Chelsea & Westminster Hospital	
Paula O'Grady	Administrator, National Institute for Health and Care Excellence	Present for all notes 01 to 34
Mr Malcolm Oswald	Lay Member	Present for all notes 01 to 34
Dr Paula Parvulescu	Public Health Physician Liverpool	Present for all notes 01 to 34
Claire Rothery	ERG representative, York	Present for notes 26 - 34
Pedro Saramago	ERG representative, York	Present for notes 26 to 34
Dr Mohit Sharma	Public Health Physician Public Health England	Present for all notes 01 to 34
L. Mary Smith	Vice President, Product Development, United Therapeutics	Present for notes 26 to 34
Dr Yvonne Summers	Clinical Expert The Christie NHS Foundation Trust	Present for notes 1 to 15
Nwamaka Umeweni	Technical Adviser, National Institute for Health and Care Excellence	Present for notes 16 to 34
Non-public observers:		
Ann Greenwood	Senior Medical Editor, National Institute for Health and Care Excellence	Present for notes 01 to 25
Dr Alexander Mathioudakis	European Respiratory Society, NICE Research Fellow	Present for notes 01 to 25
Laura Norburn	Senior Manager - Shared Decision Making, Public Involvement Programme (PIP), National Institute for Health and Care Excellence	Present for notes 01 to 15
Hiral Shah	Technical Analyst, Scientific Advice, National Institute for Health and Care Excellence	Present for notes 01 to 15

Notes

Welcome

1. The Chair welcomed all members of the Committee and other attendees present to the meeting. The Chair reviewed the agenda and timescales for the meeting, which included the appraisals of osimertinib for treating metastatic EGFR and T790M mutation-positive non-small-cell lung cancer, ramucirumab for previously treated locally advanced or metastatic non-small-cell lung cancer and dinutuximab for treating high-risk neuroblastoma
2. The Chair informed the Committee of the non-public observers at this meeting: Ann Greenwood, Alexandra Mathioudakis, Laura Norburn and Hiral Shah
3. Apologies were received from Dr Aomesh Bhatt, Dr Andrew Black, Ms Tracey Cole, Mrs Susan Dutton, Mrs Gillian Ells, Dr Susan Griffin, Professor Carol Haigh, Dr Tim Kinnaird and Professor Femi Oyebode.

Any other Business

4. None

Appraisal of osimertinib for treating metastatic EGFR and T790M mutation-positive non-small-cell lung cancer

Part 1 – Open session

5. The Chair welcomed the invited experts: Ms Karen Clayton, Dr Jesme Fox, Dr Janette Greenhalgh, James Mahon, Dr Thomas Newsom-Davis and Dr Yvonne Summers to the meeting and they introduced themselves to the Committee.
6. The Chair welcomed company representatives from AstraZeneca to the meeting.
7. The Chair asked all Committee members to declare any relevant interests
 - 7.1. Professor Gary McVeigh, Dr Lindsay Smith, Professor David Bowen, Dr Ian Campbell, Dr Ian Davidson, Professor Simon Dixon, Dr Alexander Dyker, Professor Paula Ghaneh, Professor John Henderson, Mr Malcolm Oswald, Dr Paula Parvulescu and Dr Mohit Sharma all declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of osimertinib for treating metastatic EGFR and T790M mutation-positive non-small-cell lung cancer.
 - 7.2. Dr Matthew Bradley declared a personal specific financial interest as he has shares in the company, AstraZeneca.
 - 9.3.1 It was agreed that this declaration would prevent Dr Matthew Bradley from participating in this section of the meeting.
8. The Chair asked all NICE Staff to declare any relevant interests.
 - 8.1. All declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial

interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of osimertinib for treating metastatic EGFR and T790M mutation-positive non-small-cell lung cancer.

9. The Chair asked all other invited guests to declare their relevant interests.
 - 9.1. All declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of osimertinib for treating metastatic EGFR and T790M mutation-positive non-small-cell lung cancer.
10. The Chair introduced the lead team, Professor David Bowen, Mr Malcom Oswald and Dr Mohit Sharma who gave presentations on the clinical effectiveness and cost effectiveness of osimertinib for treating metastatic EGFR and T790M mutation-positive non-small-cell lung cancer
11. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
12. The Chair explained that "representatives of the press and other members of the public be excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity on which would be prejudicial to the public interest" (Section 1(2) Public Bodies (Admission to Meetings) Act 1960)" and all public attendees left the meeting.
13. The Chair then thanked the experts and company representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

Part 2 – Closed session

14. The Committee continued to discuss the clinical and cost effectiveness of osimertinib for treating metastatic EGFR and T790M mutation-positive non-small-cell lung cancer.
 - 14.1. The committee decision was based on consensus.
15. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.

Appraisal of ramucirumab for previously treated locally advanced or metastatic non-small-cell lung cancer [ID838]

Part 1 – Open session

16. The Chair welcomed the invited experts: Dr Jesme Fox, Dr Thomas Newsom-Davis and Karen Clayton and Dr Yvonne Summers to the meeting and they introduced themselves to the Committee.
- 17.

18. The Chair welcomed company representatives from Eli Lilly to the meeting.
19. The Chair asked all Committee members to declare any relevant interests
 - 19.1. Gary McVeigh, Dr Lindsay Smith, Professor David Bowen, Dr Ian Campbell, Dr Ian Davidson, Professor Simon Dixon, Dr Alexander Dyker, Professor Paula Ghaneh, Professor John Henderson, Mr Malcolm Oswald, Dr Paula Parvulescu and Dr Mohit Sharma all declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of ramucirumab for previously treated locally advanced or metastatic non-small-cell lung cancer
 - 19.2. Professor Simon Dixon declared a non-personal specific financial interest as part of his team had produced the assessment report for this appraisal, although he had not been directly involved.
 - 9.2.1. It was agreed that this declaration would not prevent Professor Simon Dixon from participating in this section of the meeting.
20. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.
 - 20.1. Dr Jesme Fox, Dr Thomas Newsom-Davis and Karen Clayton and Dr Yvonne Summers declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of Ramucirumab for previously treated locally advanced or metastatic non-small-cell lung cancer.
21. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
22. The Chair explained that "representatives of the press and other members of the public be excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity on which would be prejudicial to the public interest" (Section 1(2) Public Bodies (Admission to Meetings) Act 1960)" and all public attendees left the meeting.
23. The Chair then thanked the experts and company representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

Part 2 – Closed session

24. The Committee continued to discuss the clinical and cost effectiveness of ramucirumab for previously treated locally advanced or metastatic non-small-cell lung cancer.
 - 24.1. The committee decision was based on consensus.

25. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

Appraisal of dinutuximab for treating high-risk neuroblastoma
Part 1 – Open session

26. The Chair welcomed company representatives from United Therapeutics to the meeting.
27. The Chair asked all Committee members to declare any relevant interests
 - 27.1. Gary McVeigh, Dr Lindsay Smith, Professor David Bowen, Dr Ian Campbell, Dr Ian Davidson, Professor Simon Dixon, Dr Alexander Dyker, Professor Paula Ghaneh, Professor John Henderson, Mr Malcolm Oswald, Dr Paula Parvulescu and Dr Mohit Sharma all declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of dinutuximab for treating high-risk neuroblastoma
28. The Chair asked all NICE Staff to declare any relevant interests.
 - 28.1. All declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of dinutuximab for treating high-risk neuroblastoma
29. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.
 - 29.1. All declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of dinutuximab for treating high-risk neuroblastoma
30. The Chair introduced the key themes arising from the consultation responses to the Appraisal Consultation Document (ACD) received from consultees, commentators and through the NICE website.
31. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
32. The Chair explained that “representatives of the press and other members of the public be excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity on which would be prejudicial to the public interest” (Section 1(2) Public Bodies (Admission to Meetings) Act 1960” and all public attendees left the meeting.

33. The Chair then thanked the experts and company representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

Part 2 – Closed session

34. The Committee continued to discuss the clinical and cost effectiveness of dinutuximab for treating high-risk neuroblastoma

34.1. The committee decision was based on consensus.

35. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

Date, time and venue of the next meeting

36. Wednesday 29 June 2016, 10:00 – 17:00 at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.