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

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 Astazeneca
Dr Ian Campbell Consultant Physician Llandough Hospital
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
Richard Diaz Technical Analyst,
                          Present for all notes 01 to 34
                          Present for notes 26 to 34
<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Notes Present For</th>
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<tbody>
<tr>
<td>Professor Simon Dixon</td>
<td>Health Economist, National Institute for Health and Care Excellence</td>
<td>01 to 34</td>
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<tr>
<td>Sally Doss</td>
<td>Technical Adviser, National Institute for Health and Clinical Excellence</td>
<td>01 to 15</td>
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<tr>
<td>Matthew Dyer</td>
<td>Health Economics Manager, Astrazeneca</td>
<td>01 to 15</td>
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<tr>
<td>Dr Alexander Dyker</td>
<td>Clinical Pharmacologist, Newcastle Hospitals Trust</td>
<td>01 to 34</td>
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<tr>
<td>Dr Jesme Fox</td>
<td>Patient Expert, Roy Castle Lung Cancer Foundation</td>
<td>01 to 15</td>
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<tr>
<td>Serban Ghiorghiu</td>
<td>Global Clinical Lead Lung Cancer, Astrazeneca</td>
<td>01 to 15</td>
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<tr>
<td>Janette Greenhalgh</td>
<td>ERG representative, LRiG</td>
<td>01 to 15</td>
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<tr>
<td>Professor Paula Ghaneh</td>
<td>Honorary Consultant Surgeon, University of Liverpool</td>
<td>01 to 34</td>
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<tr>
<td>Dr Christian Griffiths</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>01 to 15</td>
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<tr>
<td>Dr Caroline Hall</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>16 to 25</td>
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<tr>
<td>Professor John Henderson</td>
<td>Paediatrician, University of Bristol</td>
<td>01 to 34</td>
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<tr>
<td>Urpo Kiiskinen</td>
<td>Health Economics Advisor, Eli Lilly</td>
<td>16 to 25</td>
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<tr>
<td>Helen Knight</td>
<td>Associate Director, National Institute for Health and Care Excellence</td>
<td>01 to 34</td>
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<tr>
<td>James Mahon</td>
<td>ERG representative, LRiG</td>
<td>01 to 15</td>
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<tr>
<td>Fiona Maxwell</td>
<td>Medical Advisor, Eli Lilly</td>
<td>16 to 25</td>
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<tr>
<td>Kate Moore</td>
<td>Project Manager, National Institute for Health and Care Excellence</td>
<td>01 to 34</td>
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<tr>
<td>Dr Thomas Newsom-</td>
<td>Clinical Expert</td>
<td>1 to 15</td>
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<thead>
<tr>
<th>Name</th>
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<tbody>
<tr>
<td>Davis</td>
<td>Chelsea &amp; Westminster Hospital</td>
<td>Present for all notes 01 to 34</td>
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<tr>
<td>Paula O'Grady</td>
<td>Administrator, National Institute for Health and Care Excellence</td>
<td>Present for all notes 01 to 34</td>
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<tr>
<td>Mr Malcolm Oswald</td>
<td>Lay Member</td>
<td>Present for all notes 01 to 34</td>
</tr>
<tr>
<td>Dr Paula Parvulescu</td>
<td>Public Health Physician, Liverpool</td>
<td>Present for all notes 01 to 34</td>
</tr>
<tr>
<td>Claire Rothery</td>
<td>ERG representative, Liverpool</td>
<td>Present for notes 26 - 34</td>
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<tr>
<td>Pedro Saramago</td>
<td>ERG representative, York</td>
<td>Present for notes 26 to 34</td>
</tr>
<tr>
<td>Dr Mohit Sharma</td>
<td>Public Health Physician, Public Health England</td>
<td>Present for all notes 01 to 34</td>
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<tr>
<td>L. Mary Smith</td>
<td>Vice President, Product Development, United Therapeutics</td>
<td>Present for notes 26 to 34</td>
</tr>
<tr>
<td>Dr Yvonne Summers</td>
<td>Clinical Expert The Christie NHS Foundation Trust</td>
<td>Present for notes 1 to 15</td>
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<tr>
<td>Nwamaka Umeweni</td>
<td>Technical Adviser, National Institute for Health and Care Excellence</td>
<td>Present for notes 16 to 34</td>
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**Non-public observers:**

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<tr>
<th>Name</th>
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<tbody>
<tr>
<td>Ann Greenwood</td>
<td>Senior Medical Editor, National Institute for Health and Care Excellence</td>
<td>Present for notes 01 to 25</td>
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<tr>
<td>Dr Alexander Mathioudakis</td>
<td>European Respiratory Society, NICE Research Fellow</td>
<td>Present for notes 01 to 25</td>
</tr>
<tr>
<td>Laura Norburn</td>
<td>Senior Manager - Shared Decision Making, Public Involvement Programme (PIP), National Institute for Health and Care Excellence</td>
<td>Present for notes 01 to 15</td>
</tr>
<tr>
<td>Hiral Shah</td>
<td>Technical Analyst, Scientific Advice, National Institute for Health and Care Excellence</td>
<td>Present for notes 01 to 15</td>
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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.
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.