Technology Appraisal Committee Meeting (Committee D)

Minutes: Confirmed

Date and Time: Wednesday 11 April 2018, 10:00-17:00

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

Present: 1. Prof Gary McVeigh, Chair Present for all notes
          2. Dr Lindsay Smith, Vice Chair Present for all notes
          3. Dr Nabeel Alsindi Present for all notes
          4. Dr Aomesh Bhatt Present for all notes
          5. Dr Matthew Bradley Present for all notes
          6. Prof John Cairns Present for all notes
          7. Prof Paula Ghaneh Present for all notes
          8. Dr Rebecca Harmston Present for all notes
          9. Dr Robert Hodgson Present for all notes
         10. Dr Bernard Khoo Present for all notes
         11. Dr David Meads Present for all notes
         12. Libby Mills Present for all notes
         13. Prof Stephen O’Brien Present for all notes
         14. Malcolm Oswald Present for all notes
         15. Dr Paula Parvulescu Present for all notes
         16. Pam Rees Present for all notes

In attendance:

Ismahan Abdullah Administrator, National Institute for Health and Care Excellence Present for all notes

Nigel Armstrong ERG Representative, Kleijnen Systematic Reviews Present for notes 40 to 48

Nicholas Bird Patient Expert, nominated by Solving Kids’ Cancer Europe Present for notes 18 to 26

Anna Brett Technical Analyst, National Institute for Health and Care Excellence Present for notes 18 to 29

Prof Peter Clark CDF Clinical Lead, NHS England Present for all notes
<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
<th>Notes Present:</th>
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</thead>
<tbody>
<tr>
<td>Ross Dent</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>30 to 39</td>
</tr>
<tr>
<td>Dr Martin Eatock</td>
<td>Clinical Expert, nominated by Pfizer</td>
<td>1 to 14</td>
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<tr>
<td>Dr Martin Elliott</td>
<td>Clinical Expert, nominated by the Children's Cancer and Leukaemia Group and NIHR</td>
<td>18 to 26</td>
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<tr>
<td>Dr Juliet Gray</td>
<td>Clinical Expert, nominated by the Children's Cancer and Leukaemia Group and NIHR</td>
<td>18 to 26</td>
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<tr>
<td>Ed Griffin</td>
<td>AG Representative, PenTAG</td>
<td>1 to 14</td>
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<tr>
<td>Christian Griffiths</td>
<td>Technical Adviser, National Institute for Health and Care Excellence</td>
<td>40 to 51</td>
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<tr>
<td>Tony Heddon</td>
<td>Patient Expert, nominated by Neuroblastoma UK</td>
<td>18 to 26</td>
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<tr>
<td>Helen Knight</td>
<td>Associate Director, National Institute for Health and Care Excellence</td>
<td>All notes</td>
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<tr>
<td>Aimely Lee</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>1 to 17</td>
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<tr>
<td>Kate Moore</td>
<td>Project Manager, National Institute for Health and Care Excellence</td>
<td>All notes</td>
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<tr>
<td>Ruben Mujica Mota</td>
<td>AG Representative, PenTAG</td>
<td>1 to 14</td>
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<tr>
<td>Becky Pennington</td>
<td>DSU Representative, ScHARR</td>
<td>18 to 26</td>
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<tr>
<td>Kate Ren</td>
<td>DSU Representative, ScHARR</td>
<td>18 to 26</td>
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<tr>
<td>Name</td>
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<tr>
<td>Thomas Strong</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>40 to 51</td>
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<tr>
<td>Lulieth Torres</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>30 to 39</td>
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<tr>
<td>Nwamaka Umeweni</td>
<td>Technical Adviser, National Institute for Health and Care Excellence</td>
<td>1 to 29</td>
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<tr>
<td>Prof Juan Valle</td>
<td>Clinical Expert, nominated by Royal College of Physicians</td>
<td>1 to 14</td>
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<tr>
<td>Jo Varley-Campbell</td>
<td>AG Representative, PenTAG</td>
<td>1 to 14</td>
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<tr>
<td>Ashley West</td>
<td>Administrator, National Institute for Health and Care Excellence</td>
<td>All</td>
</tr>
<tr>
<td>Mark Zwanziger</td>
<td>Patient Expert, nominated by NET Patient Foundation</td>
<td>1 to 14</td>
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**Non-public observers:**

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<thead>
<tr>
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<th>Present Notes</th>
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<tbody>
<tr>
<td>Rebecca Brown</td>
<td>Analyst, NIHR Innovation Observatory</td>
<td>All</td>
</tr>
<tr>
<td>Ann Greenwood</td>
<td>Senior Editor, National Institute for Health and Care Excellence</td>
<td>All</td>
</tr>
<tr>
<td>Christian Griffiths</td>
<td>Technical Advisor, National Institute for Health and Care Excellence</td>
<td>30 to 39</td>
</tr>
<tr>
<td>Linda Landells</td>
<td>Associate Director, National Institute for Health and Care Excellence</td>
<td>40 to 51</td>
</tr>
<tr>
<td>Jane Newton</td>
<td>Head of NICE Sponsor Team, Department of Health and Social Care</td>
<td>1 to 29</td>
</tr>
<tr>
<td>Louise Tanner</td>
<td>NIHR Innovation Observatory</td>
<td>All</td>
</tr>
<tr>
<td>Maroulla Whitely</td>
<td>Costings, National Institute for Health and Care Excellence</td>
<td>All</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 177 Lu-dotatate for treating unresectable or metastatic neuroendocrine tumours in people with progressive disease, dinutuximab beta for treating high-risk neuroblastoma, atezolizumab for treating metastatic urothelial cancer after platinum-based chemotherapy and nivolumab for treating metastatic or unresectable urothelial cancer after platinum-based chemotherapy.

2. The Chair thanked Prof John Cairns (Committee B), Prof Stephen O’Brien (Committee C) and Pam Rees (Committee A) for attending this meeting to ensure quoracy.

3. The Chair informed the Committee of the non-public observers at this meeting: Rebecca Brown, Ann Greenwood, Linda Landells, Jane Newton, Louise Tanner and Maroulla Whitely.

4. Apologies were received from Prof David Bowen, Susan Dutton, Prof Rachel Elliott, Gillian Ells, Dr Peter Hall, Sumithra Maheswaran and Prof Oluwafemi Oyebode.

Any other Business

5. None.

Appraisal of 177 Lu-dotatate for treating unresectable or metastatic neuroendocrine tumours in people with progressive disease [ID1224]

Part 1 – Open session

6. The Chair welcomed the invited experts: Prof Peter Clark, Dr Martin Eatock, Ed Griffin, Ruben Mujica Mota, Prof Juan Valle, Jo Varley-Campbell and Mark Zwanziger, to the meeting and they introduced themselves to the Committee.

7. The Chair welcomed company representatives from Advanced Accelerator Applications (AAA) to the meeting.

8. The Chair asked all Committee members to declare any relevant interests

8.1. Dr Nabeel Alsindi, Dr Aomesh Bhatt, Dr Matthew Bradley, Prof Paula Ghanem, Dr Rebecca Harmston, Dr Robert Hodgson, Dr Bernard Khoo, Prof Gary McVeigh (Chair), Dr David Meads, Libby Mills, Prof Stephen O’Brien, Mr Malcolm Oswald, Dr Paula Parvulescu, Pam Rees and Dr Lindsay Smith (Vice Chair) 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 177 Lu-dotatate for treating unresectable or metastatic neuroendocrine tumours in people with progressive disease.
8.2. Prof John Cairns declared a personal non-specific financial interest as he received a payment for participating in a “Multi Criteria Decision Analysis workshop” on 12-13 March 2018. The contractor was LSE Enterprise Ltd. The workshop focused on non-alcoholic steatohepatitis (NASH) compounds and was funded by Novartis Pharma AG, who make everolimus (a comparator in this appraisal).

9.2.1 It was agreed that this declaration would not prevent Prof John Cairns from participating in this section of the meeting.

9. The Chair asked all NICE Staff to declare any 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 177 Lu-dotatate for treating unresectable or metastatic neuroendocrine tumours in people with progressive disease.

10. The Chair asked all other invited guests to declare their relevant interests.

10.1. 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 177 Lu-dotatate for treating unresectable or metastatic neuroendocrine tumours in people with progressive disease.

11. 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.

12. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.

13. 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.

14. 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

15. Discussion on confidential information continued. This information was supplied by the company.
16. The Committee continued to discuss the clinical and cost effectiveness of 177 Lu-dotatate for treating unresectable or metastatic neuroendocrine tumours in people with progressive disease.

16.1. The committee decision was based on consensus.

17. The Committee instructed the technical team to prepare an Appraisal Consultation Document (ACD in line with their decisions.

**Appraisal of dinutuximab beta for treating high-risk neuroblastoma [ID910]**

**Part 1 – Open session**

18. The Chair welcomed the invited experts: Nicholas Bird, Dr Martin Elliott, Dr Juliet Gray, Tony Heddon, Becky Pennington and Kate Ren to the meeting and they introduced themselves to the Committee.

19. The Chair welcomed company representatives from EUSA Pharma to the meeting.

20. The Chair asked all Committee members to declare any relevant interests

20.1. Dr Nabeel Alsindi, Dr Aomesh Bhatt, Dr Matthew Bradley, Prof John Cairns, Prof Paula Ghaneh, Rebecca Harmston, Dr Robert Hodgson, Dr Bernard Khoo, Prof Gary McVeigh (Chair), Dr David Meads, Libby Mills, Prof Stephen O’Brien, Mr Malcolm Oswald, Dr Paula Parvulescu, Pam Rees and Dr Lindsay Smith (Vice Chair) 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 beta for treating high-risk neuroblastoma.

21. The Chair asked all NICE Staff to declare any relevant interests.

21.1. 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 beta for treating high-risk neuroblastoma.

22. The Chair asked all other invited guests to declare their relevant interests.

22.1. Nicholas Bird, Dr Martin Elliott, Tony Heddon, Becky Pennington and Kate Ren 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 beta for treating high-risk neuroblastoma.
22.2. Dr Juliet Gray declared a non-personal specific financial interest as she is speaker at a symposium sponsored by EUSA Pharma, for which her institute received funding. It was agreed that this declaration would not prevent Dr Juliet Gray from participating in this section of the meeting.

23. The Chair introduced the key themes arising from the additional evidence provided by the company.

24. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.

25. 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.

26. 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

27. Discussion on confidential information continued. This information was supplied by the company.

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

28.1. The committee decision was based on consensus.

29. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.

Appraisal of atezolizumab for treating metastatic urothelial cancer after platinum-based chemotherapy [ID1327]

Part 1 – Open session

30. The Chair welcomed company representatives from Roche to the meeting.

31. The Chair asked all Committee members to declare any relevant interests

31.1. Dr Nabeel Alsindi, Dr Aomesh Bhatt, Dr Matthew Bradley, Prof John Cairns, Prof Paula Ghaneh, Rebecca Harmston, Dr Robert Hodgson, Dr Bernard Khoo, Prof Gary McVeigh (Chair), Dr David Meads, Libby Mills, Prof Stephen O’Brien, Mr Malcolm Oswald, Dr Paula Parvulescu, Ms Pam Rees and Dr Lindsay Smith (Vice Chair) 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 atezolizumab for treating metastatic urothelial cancer after platinum-based chemotherapy.

32. The Chair asked all NICE Staff to declare any relevant interests.

32.1. 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 atezolizumab for treating metastatic urothelial cancer after platinum-based chemotherapy.

33. 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.

34. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.

35. 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.

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

Part 2 – Closed session

37. Discussion on confidential information continued. This information was supplied by the company.

38. The Committee continued to discuss the clinical and cost effectiveness of atezolizumab for treating metastatic urothelial cancer after platinum-based chemotherapy.

38.1. The committee decision was based on consensus.

39. The Committee instructed the technical team to prepare an Appraisal Consultation Document (ACD) in line with their decisions.

Appraisal of nivolumab for treating metastatic or unresectable urothelial cancer after platinum-based chemotherapy [ID995]

Part 1 – Open session

40. The Chair welcomed the invited expert, Nigel Armstrong, to the meeting and they introduced themselves to the Committee.

41. The Chair welcomed company representatives from Bristol-Myers Squibb to the meeting.
42. The Chair asked all Committee members to declare any relevant interests

42.1. Dr Nabeel Alsindi, Dr Aomesh Bhatt, Dr Matthew Bradley, Prof John Cairns, Prof Paula Ghaneh, Rebecca Harmston, Dr Robert Hodgson, Dr Bernard Khoo, Prof Gary McVeigh (Chair), Dr David Meads, Libby Mills, Prof Stephen O’Brien, Mr Malcolm Oswald, Dr Paula Parvulescu, Ms Pam Rees and Dr Lindsay Smith (Vice Chair) 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 nivolumab for treating metastatic or unresectable urothelial cancer after platinum-based chemotherapy.

43. The Chair asked all NICE Staff to declare any relevant interests.

43.1. 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 nivolumab for treating metastatic or unresectable urothelial cancer after platinum-based chemotherapy.

44. The Chair asked all other invited guests to declare their relevant interests.

44.1. 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 nivolumab for treating metastatic or unresectable urothelial cancer after platinum-based chemotherapy.

45. The Chair introduced the key themes arising from the new evidence submitted by the company.

46. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.

47. 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.

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

Part 2 – Closed session
49. Discussion on confidential information continued. This information was supplied by
the company.

50. The Committee continued to discuss the clinical and cost effectiveness of
nivolumab for treating metastatic or unresectable urothelial cancer after platinum-
based chemotherapy.

50.1. The committee decision was based on consensus.

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

Date, time and venue of the next meeting

52. Tuesday 15 May 2018, 10:00, at National Institute for Health and Care Excellence,
Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.