

## 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

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

Ross Dent	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 30 to 39
Dr Martin Eatock	Clinical Expert, nominated by Pfizer	Present for notes 1 to 14
Dr Martin Elliott	Clinical Expert, nominated by the Children's Cancer and Leukaemia Group and NIHR	Present for notes 18 to 26
Dr Juliet Gray	Clinical Expert, nominated by the Children's Cancer and Leukaemia Group and NIHR	Present for notes 18 to 26
Ed Griffin	AG Representative, PenTAG	Present for notes 1 to 14
Christian Griffiths	Technical Adviser, National Institute for Health and Care Excellence	Present for notes 40 to 51
Tony Heddon	Patient Expert, nominated by Neuroblastoma UK	Present for notes 18 to 26
Helen Knight	Associate Director, National Institute for Health and Care Excellence	Present for all notes
Aimely Lee	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 1 to 17
Kate Moore	Project Manager, National Institute for Health and Care Excellence	Present for all notes
Ruben Mujica Mota	AG Representative, PenTAG	Present for notes 1 to 14
Becky Pennington	DSU Representative, ScHARR	Present for notes 18 to 26
Kate Ren	DSU Representative, ScHARR	Present for notes 18 to 26

Thomas Strong	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 40 to 51
Lulieth Torres	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 30 to 39
Nwamaka Umeweni	Technical Adviser, National Institute for Health and Care Excellence	Present for notes 1 to 29
Prof Juan Valle	Clinical Expert, nominated by Royal College of Physicians	Present for notes 1 to 14
Jo Varley-Campbell	AG Representative, PenTAG	Present for notes 1 to 14
Ashley West	Administrator, National Institute for Health and Care Excellence	Present for all notes
Mark Zwanziger	Patient Expert, nominated by NET Patient Foundation	Present for notes 1 to 14

**Non-public observers:**

Rebecca Brown	Analyst, NIHR Innovation Observatory	Present for all notes
Ann Greenwood	Senior Editor, National Institute for Health and Care Excellence	Present for all notes
Christian Griffiths	Technical Advisor, National Institute for Health and Care Excellence	Present for notes 30 to 39
Linda Landells	Associate Director, National Institute for Health and Care Excellence	Present for notes 40 to 51
Jane Newton	Head of NICE Sponsor Team, Department of Health and Social Care	Present for notes 1 to 29
Louise Tanner	NIHR Innovation Observatory	Present for all notes
Maroulla Whitely	Costings, National Institute for Health and Care Excellence	Present for all notes

## 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 Ghaneh, 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-diotate 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.
  - 22.2.1. 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.