# **Technology Appraisal Committee Meeting (Committee D)**

Minutes: Confirmed

Date and Time: Tuesday 12 June 2018, 10am – 4pm

**Venue:** National Institute for Health and Care Excellence

Level 1A, City Tower Piccadilly Plaza Manchester M1 4BT

**Present:** 1. Professor 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. Michael Chambers Present for all notes 6. Prithwirai Das Present for all notes 7. Professor Rachel Elliott Present for all notes 8. Gillian Ells Present for all notes 9. Professor Paula Ghaneh Present for all notes 10. Dr Peter Hall Present for all notes 11. Rebecca Harmston Present for all notes

12. Dr Robert Hodgson Present for notes 16 to 38

13. Dr Bernard KhooPresent for all notes14. Libby MillsPresent for all notes15. Dr Malcolm OswaldPresent for all notes16. Dr Paula ParvulescuPresent for all notes

#### In attendance:

Ismahan Abdullah Administrator, National Present for all notes

Institute for Health and

Care Excellence

Anna Brett Technical Analyst, Present for notes 16 to 27

National Institute for Health and Care

Excellence

Simon Butler Patient Expert, Present for notes 1 to 12

nominated by Anthony

Nolan

Professor Peter Clark CDF

Rob Coster

CDF lead, NHS England NHS Commissioning

expert, nominated by

NHS England

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Dr Robert Danby Clinical expert, Present for notes 1 to 12

nominated by Anthony

Nolan

Dr Martin Elliott Clinical expert, Present for points16 to 24

nominated by Children's Cancer and Leukaemia

Group (CCLG)

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Present for notes 16 to 38

Present for notes 1 to 12

Dr Juliet Gray	Clinical expert, nominated by Children's Cancer and Leukaemia	Present for points16 to 24
Christian Griffiths	Group (CCLG) Technical Adviser, National Institute for Health and Care Excellence	Present for notes 1 to 15
Tony Heddon	Patient Expert, nominated by Neuroblastoma UK	Present for points16 to 24
Helen Knight	Associate Director, National Institute for Health and Care Excellence	Present for all notes
Linda Landells	Associate Director, CDF, National Institute for Health and Care Excellence	Present for notes 16 to 27
Aimely Lee	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 1 to 15 and 25 to 38
Kate Moore	Project Manager, National Institute for Health and Care Excellence	Present for all notes
Joanne O'Connor	ERG representative, Centre for Reviews and Dissemination and Centre for Health	Present for notes 1 to 12
Professor Karl Peggs	Economics – York Clinical expert, nominated by Merck Sharp & Dohme and Anthony Nolan	Present for notes 1 to 12
Becky Pennington	Decision Support Unit representative	Present for notes 16 to 24
Kate Ren	Decision Support Unit representative	Present for notes 16 to 24
Professor Steve Rothberg	Patient Expert, nominated by Anthony Nolan	Present for notes 1 to 12
Thomas Strong	Technical Analyst, CDF, National Institute for Health and Care Excellence	Present for notes 16 to 27
Nwamaka Umeweni	Technical Adviser, National Institute for Health and Care Excellence	Present for notes 16 to 38
Nerys Woolacott	Centre for Reviews and Dissemination and Centre for Health Economics – York	Present for notes 1 to 12

## Non-public observers:

Fiona Beyer

Analyst, NIHR Innovation Observatory

Present for notes 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 letermovir prophylaxis for cytomegalovirus disease after allogeneic stem cell transplant, dinutuximab beta for treating highrisk neuroblastoma and lutetium (177lu) oxodotreotide for treating unresectable or metastatic neuroendocrine tumours in people with progressive disease.
- 2. Apologies were received from Professor David Bowen, Dr Matthew Bradley, Sumithra Maheswaran, Dr David Meads and Professor Femi Oyebode.

# **Any other Business**

3. None

# Appraisal of letermovir prophylaxis for cytomegalovirus disease after allogeneic stem cell transplant

# Part 1 - Open session

- 4. The Chair welcomed the invited experts: Simon Butler, Joanne O'Connor, Rob Coster, Dr Robert Danby, Professor Karl Peggs, Professor Steve Rothberg, Nerys Woolacott to the meeting and they introduced themselves to the Committee.
- 5. The Chair welcomed company representatives from Merck Sharp & Dohme to the meeting.
- 6. The Chair asked all Committee members to declare any relevant interests
  - Or Nabeel Alsindi, Dr Aomesh Bhatt, Mike Chambers, Dr Prithwiraj Das, Professor Rachel Elliott, Gillian Ells, Professor Paula Ghaneh, Dr Peter Hall, Rebecca Harmston, Robert Hodgson, Dr Bernard Khoo, Professor Gary McVeigh (Chair), Libby Mills, Dr Malcolm Oswald, Dr Paula Parvulescu and Dr Lindsay Smith (Vice Chair) all declared that they knew of no personal specific financial interest, personal non-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 letermovir prophylaxis for cytomegalovirus disease after allogeneic stem cell transplant.
  - 6.2. Dr Matthew Bradley was absent from the committee meeting as he had declared a direct financial interest as he is an employee of the comparator company.
- 7. The Chair asked all NICE Staff to declare any relevant interests.
  - 7.1. 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 letermovir prophylaxis for cytomegalovirus disease after allogeneic stem cell transplant.

- 8. The Chair asked all other invited guests to declare their 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 letermovir prophylaxis for cytomegalovirus disease after allogeneic stem cell transplant.
- 9. The Chair introduced the lead team, Dr Bernard Khoo, Malcolm Oswald and Dr Paula Parvulescu who gave presentations on the clinical effectiveness and cost effectiveness of letermovir prophylaxis for cytomegalovirus disease after allogeneic stem cell transplant.
- 10. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
- 11. 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.
- 12. 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

- 13. Discussion on confidential information continued. This information was supplied by the company.
- 14. The Committee continued to discuss the clinical and cost effectiveness of letermovir prophylaxis for cytomegalovirus disease after allogeneic stem cell transplant.
  - 14.1. A vote was taken. The options were:

**Option 1:** to recommend letermovir, within its marketing authorisation, for preventing cytomegalovirus (CMV) reactivation or disease after an allogeneic haematopoietic stem cell transplant (HSCT) in adults who are seropositive for CMV

**Option 2:** to not recommend letermovir, within its marketing authorisation, for preventing CMV reactivation or disease after an allogeneic HSCT in adults who are seropositive for CMV

14.1.1. The Committee voted for Option 2.

15. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) or Final Appraisal Determination (FAD) in line with their decisions.

# Appraisal of dinutuximab beta for treating high-risk neuroblastoma

# Part 1 - Open session

- 16. The Chair welcomed the invited experts: Professor Peter Clark, Dr Martin Elliott, Dr Juliet Grey, Tony Heddon, Becky Pennington and Kate Ren to the meeting and they introduced themselves to the Committee.
- 17. The Chair welcomed company representatives from EUSA Pharma to the meeting.
- 18. The Chair asked all Committee members to declare any relevant interests
  - 18.1. Dr Nabeel Alsindi, Dr Aomesh Bhatt, Mike Chambers, Prithwiraj Das, Professor Rachel Elliott, Gillian Ells, Professor Paula Ghaneh, Rebecca Harmston, Dr Robert Hodgson, Dr Bernard Khoo, Professor Gary McVeigh (Chair), Libby Mills, Dr Malcolm Oswald, Dr Paula Parvulescu and Dr Lindsay Smith (Vice Chair) all declared that they knew of no direct or indirect interests for any of the technologies to be considered as part of the appraisal of dinutuximab beta for treating high-risk neuroblastoma.
  - 18.2. Dr Peter Hall declared an indirect interest as his employer had received research funding from a comparator company, although he did not directly benefit.
    - 9.2.1 It was agreed that this declaration would not prevent Dr Peter Hall from participating in this section of the meeting.
- 19. The Chair asked all NICE Staff to declare any relevant interests.
  - 19.1. All declared that they knew of no direct or indirect interests for any of the technologies to be considered as part of the appraisal of dinutuximab beta for treating high-risk neuroblastoma.
- 20. The Chair asked all other invited guests to declare their relevant interests.
  - 20.1. All declared that they knew of no direct or indirect interests for any of the technologies to be considered as part of the appraisal of dinutuximab beta for treating high-risk neuroblastoma.
- 21. 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.
- 22. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
- 23. 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.

24. 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

- 25. Discussion on confidential information continued. This information was supplied by the company.
- 26. The Committee continued to discuss the clinical and cost effectiveness of dinutuximab beta for treating high-risk neuroblastoma.
  - 26.1. The committee decision was based on consensus.
- 27. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) or Final Appraisal Determination (FAD) in line with their decisions.

Appraisal of lutetium (177lu) oxodotreotide for treating unresectable or metastatic neuroendocrine tumours in people with progressive disease

# Part 1 - Open session

- 28. The Chair welcomed company representatives from AAA to the meeting.
- 29. The Chair asked all Committee members to declare any relevant interests
  - 29.1. Dr Nabeel Alsindi, Dr Aomesh Bhatt, Mike Chambers, Dr Prithwiraj Das, Professor Rachel Elliott, Gillian Ells, Professor Paula Ghaneh, Dr Peter Hall, Rebecca Harmston, Dr Robert Hodgson, Dr Bernard Khoo, Professor Gary McVeigh (Chair), Libby Mills, Dr Malcolm Oswald, Dr Paula Parvulescu and Dr Lindsay Smith (Vice Chair) all declared that they knew of no direct or indirect interests for any of the technologies to be considered as part of the appraisal of lutetium (177lu) oxodotreotide for treating unresectable or metastatic neuroendocrine tumours in people with progressive disease.
- 30. The Chair asked all NICE Staff to declare any relevant interests.
  - 30.1. All declared that they knew of no direct or indirect interests for any of the technologies to be considered as part of the appraisal of lutetium (177lu) oxodotreotide for treating unresectable or metastatic neuroendocrine tumours in people with progressive disease.
- 31. 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.
- 32. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
- 33. 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.
- 34. 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

- 35. Discussion on confidential information continued. This information was supplied by the company.
- 36. The Committee continued to discuss the clinical and cost effectiveness of lutetium (177lu) oxodotreotide for treating unresectable or metastatic neuroendocrine tumours in people with progressive disease.
  - 36.1. The committee decision was based on consensus.
- 37. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) or Final Appraisal Determination (FAD) in line with their decisions.

## Date, time and venue of the next meeting

38. Thursday 12 July 2018, 10am – 5pm at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.