Technology Appraisal Committee Meeting (Committee C)

Minutes: Confirmed

Date and Time: Thursday, 26 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. Chair Professor Stephen O'Brien Present for all notes
2. Dr Alex Cale Present for all notes
3. Mr Michael Chambers Present for all notes
4. Mr David Chandler Present for all notes
5. Ms Gail Coster Present for all notes
6. Dr Prithviraj Das Present for notes 9 to 39
7. Dr Natalie Hallas Present for all notes
8. Mr John Hampson Present for all notes
9. Dr Nigel Langford Present for all notes
10. Prof Andrea Manca Present for all notes
11. Dr Richard Nicholas Present for all notes
12. Dr Peter Selby Present for all notes
13. Prof Matt Stevenson Present for all notes
14. Dr Paul Tappenden Present for all notes
15. Dr Derek Ward Present for all notes
16. Dr Judith Wardle Present for all notes

In attendance:

Helen Knight Acting Programme Director, National Institute for Health and Care Excellence Present for all notes

Frances Sutcliffe Associate Director, National Institute for Health and Care Excellence Present for all notes

Stephanie Callaghan Project Manager, National Institute for Health and Care Excellence Present for all notes

Tanith Musson Administrator, National Institute for Health and Care Excellence Present for all notes

Ismahan Abdullah Administrator, National Institute for Health and Care Excellence Present for all notes
Julia Sus  
Technical Analyst, National Institute for Health and Care Excellence  
Present for notes 1 to 15

Alex Filby  
Technical Adviser, National Institute for Health and Clinical Excellence  
Present for notes 1 to 15

Abitha Senthinathan  
Technical Analyst, National Institute for Health and Care Excellence  
Present for notes 16 to 27

Sally Doss  
Technical Adviser, National Institute for Health and Clinical Excellence  
Present for notes 16 to 39

Victoria Kelly  
Technical Analyst, National Institute for Health and Care Excellence  
Present for notes 28 to 39

Non-public attendees:

Lindsay Claxton  
ERG representative  
Present for notes 4 to 12

Stephen Palmer  
ERG representative  
Present for notes 4 to 12

Ros Wade  
ERG representative  
Present for notes 4-12 & 28-36

Rui Duarte  
ERG representative  
Present for notes 16 to 24

Nigel Fleeman  
ERG representative  
Present for notes 16 to 24

Susan Griffin  
ERG representative  
Present for notes 28 to 36

Steven Knapper  
Clinical Expert  
Present for notes 4 to 12

Nigel Russel  
Clinical Expert  
Present for notes 4 to 12

Adele Fielding  
Clinical Expert  
Present for notes 28 to 36

David Marks  
Clinical Expert  
Present for notes 28 to 36

Peter Clark  
CDF Clinical lead  
Present for notes 4-12 & 28-36

Simon Purcell  
Company representative  
Present for notes 4-12 & 28-36

Darshan Zala  
Company representative  
Present for notes 4 to 12

Ioana Grobeiu  
Company representative  
Present for notes 4 to 12

Matthew Mildred  
Company representative  
Present for notes 16 to 24

Alexander Smith  
Company representative  
Present for notes 28 to 36

James Altunkaya  
NICE Observer  
Present for all notes

Lorna Dunning  
NICE Observer  
Present for all notes

Leslie Hayes  
NICE Observer  
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 gemtuzumab ozogamicin for untreated acute myeloid leukaemia [ID982], cenegecin for treating neurotrophic keratitis [ID946], and inotuzumab ozogamicin for treating relapsed or refractory B-cell acute
lymphoblastic leukaemia [ID893].

2. The Chair informed the Committee of the non-public observers at this meeting: James Altunkaya, Lorna Dunning, Leslie Hayes

3. Apologies were received from Mr Kamal Balakrishnan, Dr Rubin Minhas, Prof Andrew Renehan and Prof Robert Walton

**Appraisal of gemtuzumab ozogamicin for untreated acute myeloid leukaemia [ID982]**

**Part 1 – Open session**

4. The Chair welcomed the invited experts: Peter Clark, Lindsay Claxton, Stephen Palmer, Ros Wade, Steven Knapper and Nigel Russell to the meeting and they introduced themselves to the Committee.

5. The Chair welcomed company representatives from Pfizer to the meeting.

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

   6.1. Dr Alex Cale, Mr Michael Chambers, Ms Gail Coster, Dr Prithwiraj Das, Dr Natalie Hallas, Mr John Hampson, Dr Nigel Langford, Dr Richard Nicholas, Professor Peter Selby, Prof Matt Stevenson, Dr Paul Tappenden, Dr Derek Ward and Dr Judith Wardle 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 gemtuzumab ozogamicin for untreated acute myeloid leukaemia [ID982]

   6.2. Prof Andrea Manca declared a personal non-specific non-financial interest as he was a co-investigator in NIHR and H2020 grants on haematological malignancies. 9.2.1 It was agreed that this declaration would not prevent Prof Andrea Manca from participating in this section of the meeting.

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 gemtuzumab ozogamicin for untreated acute myeloid leukaemia [ID982]

8. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) 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, 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 gemtuzumab ozogamicin for untreated acute myeloid leukaemia [ID982]
8.2. Steven Knapper declared a non-personal non-specific non-financial interest as he has conducted studies in this disease area
8.2.1. It was agreed that this declaration would not prevent Steven Knapper from participating in this section of the meeting

8.3. Nigel Russell declared a personal non-specific financial interest as he sat on advisory boards for Pfizer
8.3.1. It was agreed that this declaration would not prevent Nigel Russell from participating in this section of the meeting

9. The Chair introduced the lead team, David Chandler, Nigel Langford and Derek Ward, who gave presentations on the clinical effectiveness and cost effectiveness of gemtuzumab ozogamicin for untreated acute myeloid leukaemia [ID982]

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 gemtuzumab ozogamicin for untreated acute myeloid leukaemia [ID982]

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

**Appraisal of cenegermin for treating neurotrophic keratitis [ID946]**

**Part 1 – Open session**

16. The Chair welcomed the invited experts: Rui Duarte and Nigel Fleeman to the meeting and they introduced themselves to the Committee.

17. The Chair welcomed company representatives from Dompe to the meeting.

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

18.1. Dr Alex Cale, Mr Michael Chambers, Ms Gail Coster, Dr Prithwiraj Das, Dr Natalie Hallas, Mr John Hampson, Dr Nigel Langford, Prof Andrea Manca, Dr Richard Nicholas, Professor Peter Selby, Prof Matt Stevenson, Dr Paul Tappenden, Dr Derek Ward and Dr Judith Wardle 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 ceneegermin for treating neurotrophic keratitis [ID946]

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

19.1. 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 ceneegermin for treating neurotrophic keratitis [ID946]

20. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.

20.1. 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 ceneegermin for treating neurotrophic keratitis [ID946]

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 ceneegermin for treating neurotrophic keratitis [ID946]

26.1. The committee decision was based on consensus.

27. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.
Appraisal of inotuzumab ozogamicin for treating relapsed or refractory B-cell acute lymphoblastic leukaemia [ID893]

Part 1 – Open session

28. The Chair welcomed the invited experts: Peter Clark, Susan Griffin, Ros Wade, Adele Fielding and David Marks to the meeting and they introduced themselves to the Committee.

29. The Chair welcomed company representatives from Pfizer to the meeting.

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

30.1. Dr Alex Cale, Mr Michael Chambers, Ms Gail Coster, Dr Prithwiraj Das, Dr Natalie Hallas, Mr John Hampson, Dr Nigel Langford, Dr Richard Nicholas, Professor Peter Selby, Prof Matt Stevenson, Dr Paul Tappenden, Dr Derek Ward and Dr Judith Wardle 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 inotuzumab ozogamicin for treating relapsed or refractory B-cell acute lymphoblastic leukaemia [ID893]

30.2. Prof Andrea Manca declared a personal non-specific non-financial interest as he was a co-investigator in NIHR and H2020 grants on haematological malignancies

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

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

31.1. 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 inotuzumab ozogamicin for treating relapsed or refractory B-cell acute lymphoblastic leukaemia [ID893]

32. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their 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 inotuzumab ozogamicin for treating relapsed or refractory B-cell acute lymphoblastic leukaemia [ID893]

32.2. Adele Fielding declared a personal non-specific financial interest as she has sat on advisory boards for Pfizer

32.2.1. It was agreed that this declaration would not prevent Adele Fielding from participating in this section of the meeting.
32.3. David Marks declared a personal non-specific financial interest as he has sat on advisory boards for Pfizer and also has ongoing academic collaborations with Pfizer.

32.3.1. It was agreed that this declaration would not prevent David Marks from participating in this section of the meeting.

33. The Chair introduced the key themes for consideration arising from the appeal points.

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 experts and 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 inotuzumab ozogamicin for treating relapsed or refractory B-cell acute lymphoblastic leukaemia [ID893]

38.1. The committee decision was based on consensus.

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

Date, time and venue of the next meeting

40. Wednesday 30 May 2018 at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.