

## 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

<b>Present:</b>	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 Prithwiraj 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 16 to 24
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], cenegermin 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, 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]

- 8.2. 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 cenegermin 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 cenegermin 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 cenegermin 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 cenegermin 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.