

## Technology Appraisal Committee Meeting (Committee C)

**Minutes:** Confirmed

**Date and Time:** Wednesday 27 June 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. Mr Kamal Balakrishnan	Present for all notes
	3. Mr David Chandler	Present for all notes
	4. Ms Gail Coster	Present for all notes
	5. Dr Prithwiraj Das	Present for all notes
	6. Dr Natalie Hallas	Present for all notes
	7. Mr John Hampson	Present for all notes
	8. Dr Nigel Langford	Present for all notes
	9. Prof Andrea Manca	Present for all notes
	10. Dr Rubin Minhas	Present for all notes
	11. Prof Andrew Renehan	Present for all notes
	12. Dr Peter Selby	Present for notes 1 to 16
	13. Prof Matt Stevenson	Present for all notes
	14. Dr Paul Tappenden	Present for notes 17 to 40
	15. Dr Derek Ward	Present for all notes
	16. Dr Judith Wardle	Present for all notes

### In attendance:

Helen Knight	Programme Director, National Institute for Health and Care Excellence	Present for all notes
Dr Frances Sutcliffe	Associate Director, National Institute for Health and Care Excellence	Present for notes 17 to 40
Sheela Upadhyaya	Associate Director, National Institute for Health and Care Excellence	Present for notes 1 to 16

Joanne Ekeledo	Project Manager, National Institute for Health and Care Excellence	Present for notes 1 to 16
Stephanie Callaghan	Project Manager, National Institute for Health and Care Excellence	Present for notes 17 to 40
Mandy Tonkinson	Administrator, National Institute for Health and Care Excellence	Present for notes 1 to 16
Ismahan Abdullah	Administrator, National Institute for Health and Care Excellence	Present for notes 17 to 40
Lulieth Torres	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 1 to 16
Ian Watson	Technical Advisor, National Institute for Health and Care Excellence	Present for notes 1 to 16
Julia Sus	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 17 to 28
Nicola Hay	Technical Advisor, National Institute for Health and Care Excellence	Present for notes 17 to 28
Victoria Kelly	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 29 to 40
Sally Doss	Technical Advisor, National Institute for Health and Care Excellence	Present for notes 29 to 40

**Non-public attendees:**

Jean Hamilton	ERG Representative	Present for notes 1 to 13
Emma Hock	ERG Representative	Present for notes 1 to 13
Stephen Palmer	ERG Representative	Present for notes 17 to 25
Mark Simmonds	ERG Representative	Present for notes 17 to 25
Paul Tappenden	ERG Representative	Present for notes 1 to 13
Gennadiy Ilyashenko	Patient Expert	Present for notes 1 to 13
Liz Lockley	Patient Expert	Present for notes 1 to 13
Adnan Manzur	Clinical Expert	Present for notes 1 to 13
Fiona Marley	NHSE Commissioning Expert	Present for notes 1 to 13
Wojtek Rakowicz	Clinical Expert	Present for notes 1 to 13
Liz Ryburn	Patient Expert	Present for notes 1 to 13
David Thomson	CDF clinical lead NHSE Commissioning	Present for notes 17 to 40
Malcolm Qualie	Expert Company Representative	Present for notes 1 to 13
Tiago Fonseca	Company Representative	Present for notes 17 to 25
Simon Purcell	Company Representative	Present for notes 17 to 25
Alexander Smith	Company Representative	Present for notes 29 to 37
Michael Tempest	Company Representative	Present for notes 1 to 16
Ben Tichler	NICE Observer	Present for notes 1 to 16
Sally Doss	NICE Observer	Present for notes 17 to 28
Grace Jennings	NICE Observer	Present for notes 1 to 16
Heidi Livingstone	NICE Observer	Present for notes 1 to 16
Gary Shield	NICE Observer	Present for notes 1 to 40
Thomas Strong	NICE Observer	Present for notes 1 to 16
Frances Sutcliffe	NICE Observer	Present for notes 1 to 16
Karen Facey	External Observer	Present for notes 1 to 16
Andrew Rawdin	External Observer	Present for notes 1 to 16
Ruth Walker		Present for notes 17 to 28

## Notes

Jean Hamilton, Emma Hock, Stephen Palmer, Mark Simmonds, Paul Tappenden, Gennadiy Ilyashenko, Liz Lockley, Adnan Manzur, Fiona Marley, Wojtek Rakowicz and Liz Ryburn

## 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 nusinersen for treating spinal muscular atrophy [ID1069], gemtuzumab ozogamicin for untreated acute myeloid leukaemia [ID982] 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: Sally Doss, Grace Jennings, Heidi Livingstone, Gary Shield, Thomas Strong and Frances Sutcliffe.
3. Apologies were received from Dr Alex Cale, Mr Michael Chambers, Dr Richard Nicholas and Prof Robert Walton

## **Any other Business**

4. None

## **Appraisal of nusinersen for treating spinal muscular atrophy [ID1069]**

### **Part 1 – Open session**

5. The Chair welcomed the invited experts: Jean Hamilton, Emma Hock, Stephen Palmer, Mark Simmonds, Paul Tappenden, Gennadiy Ilyashenko, Liz Lockley, Adnan Manzur, Fiona Marley, Wojtek Rakowicz and Liz Ryburn to the meeting and they introduced themselves to the Committee.
6. The Chair welcomed company representatives from Biogen to the meeting.
7. The Chair asked all Committee members to declare any relevant interests
  - 7.1. Dr Kamal Balakrishnan, Mr David Chandler, Ms Gail Coster, Dr Prithwiraj Das, Dr Natalie Hallas, Mr John Hampson, Dr Nigel Langford, Prof Andrea Manca, Dr Rubin Minhas, Prof Andrew Renehan, 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 nusinersen for treating spinal muscular atrophy.
  - 7.2. Prof Matt Stevenson declared a non-personal specific financial interest as part of his team had produced the assessment report for this appraisal, although he had not been directly involved.
    - 7.2.1. It was agreed that this declaration would not prevent Prof Matt Stevenson from participating in this section of the meeting.
8. The Chair asked all NICE Staff to declare any 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 nusinersen for treating spinal muscular atrophy.
9. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.
  - 9.1. Jean Hamilton, Emma Hock, Stephen Palmer, Mark Simmonds, Paul Tappenden, Liz Lockley, Fiona Marley, Wojtek Rakowicz and Liz Ryburn 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 nusinersen for treating spinal muscular atrophy.

- 9.2. Dr Adnan Manzur declared a personal financial interest as he provided consultancy for Biogen in respect of SMA
  - 9.2.1. It was agreed that this declaration would not prevent Dr Adnan Manzur from participating in this section of the meeting
- 9.3. Gennadiy Ilyashenko declared a personal non- financial interest as he is a Board member of TreatSMA.
  - 9.3.1. It was agreed that this declaration would not prevent Gennadiy Ilyashenko from participating in this section of the meeting
10. The Chair introduced the lead team, Dr Kamal Balakrishnan, David Chandler and Prof Andrea Manca who gave presentations on the clinical effectiveness and cost effectiveness of nusinersen for treating spinal muscular atrophy.
11. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
12. 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.
13. 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**

14. Discussion on confidential information continued. This information was supplied by the company.
15. The Committee continued to discuss the clinical and cost effectiveness of nusinersen for treating spinal muscular atrophy.
  - 15.1. The committee decision was based on consensus.
16. 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 Gemtuzumab ozogamicin for untreated acute myeloid leukaemia [ID982]**

### **Part 1 – Open session**

17. The Chair welcomed the invited experts: Stephen Palmer, Mark Simmonds, David Thomson to the meeting and they introduced themselves to the Committee.
18. The Chair welcomed company representatives from Pfizer to the meeting.
19. The Chair asked all Committee members to declare any relevant interests

- 19.1. Dr Kamal Balakrishnan, Mr David Chandler, Ms Gail Coster, Dr Prithwiraj Das, Dr Natalie Hallas, Mr John Hampson, Dr Nigel Langford, Dr Rubin Minhas, Prof Andrew Renehan, 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.
- 19.2. Prof Andrea Manca declared a personal specific non-financial interest as he is a co-investigator in NIHR and received H2020 grants on haematological malignancies
  - 19.2.1. It was agreed that this declaration would not prevent Prof Andrea Manca from participating in this section of the meeting.
20. The Chair asked all NICE Staff to declare any 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 Gemtuzumab ozogamicin for untreated acute myeloid leukaemia.
21. The Chair asked all other invited guests to declare their 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 Gemtuzumab ozogamicin for untreated acute myeloid leukaemia
22. 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.
23. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
24. 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.
25. 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**

26. Discussion on confidential information continued. This information was supplied by the company.
27. The Committee continued to discuss the clinical and cost effectiveness of Gemtuzumab ozogamicin for untreated acute myeloid leukaemia [ID982]
  - 27.1. The committee decision was based on consensus.
28. The Committee agreed to defer a decision on the content of the guidance section of the Final Appraisal Document (FAD) following receipt of further analyses. The committee will continue its decision making as a short agenda item at the meeting on Wednesday 22 August 2018.

### **Appraisal of Inotuzumab ozogamicin for treating relapsed or refractory B-cell acute lymphoblastic leukaemia [ID893]**

#### **Part 1 – Open session**

29. The Chair welcomed the invited experts: David Thomson to the meeting and he introduced himself to the Committee.
30. The Chair welcomed company representatives from Pfizer to the meeting.
31. The Chair asked all Committee members to declare any relevant interests
  - 31.1. Dr Kamal Balakrishnan, Mr David Chandler, Ms Gail Coster, Dr Prithwiraj Das, Dr Natalie Hallas, Mr John Hampson, Dr Nigel Langford, Dr Rubin Minhas, Prof Andrew Renehan, 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.
  - 31.2. Prof Andrea Manca declared a personal specific non-financial interest as he is a co-investigator in NIHR and received H2020 grants on haematological malignancies
    - 31.2.1. It was agreed that this declaration would not prevent Prof Andrea Manca from participating in this section of the meeting.
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 Inotuzumab ozogamicin for treating relapsed or refractory B-cell acute lymphoblastic leukaemia.
33. The Chair asked all other invited guests to declare their relevant interests.

- 33.1. 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.
34. 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.
35. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
36. 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.
37. 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**

38. Discussion on confidential information continued. This information was supplied by the company.
39. The Committee continued to discuss the clinical and cost effectiveness of Inotuzumab ozogamicin for treating relapsed or refractory B-cell acute lymphoblastic leukaemia.
- 39.1. The committee decision was based on consensus.
40. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

## **Date, time and venue of the next meeting**

41. Tuesday 31 July 2018 at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.