Technology Appraisal Committee Meeting (Committee C)

Minutes: Confirmed

Date and Time: Tuesday 16 May 2017, 10:00 to 18:00

Venue: National Institute for Health and Care Excellence
Level 1A, City Tower
Piccadilly Plaza
Manchester
M1 4BT

Present:
1. Chair Professor Andrew Stevens Present for all notes
2. Professor Kathryn Abel Present for all notes
3. Mr Kamal Balakrishnan Present for all notes
4. Mr Michael Chambers Present for all notes
5. Mr David Chandler Present for all notes
6. Mrs Gail Coster Present for all notes
7. Dr Prithwiraj Das Present for all notes
8. Mr John P Hampson Present for all notes
9. Dr Nigel Langford Present for all notes
10. Professor Andrea Manca Present for all notes
11. Dr Iain Miller Present for all notes
12. Professor Andrew Renehan Present for all notes
13. Professor Stephen O'Brien Present for all notes
14. Professor Peter Selby Present for all notes
15. Professor Matt Stevenson Present for notes 4 to 26 and 39 to 49
16. Dr Paul Tappenden Present for all notes
17. Mr Robert Walton Present for all notes
18. Dr Judith Wardle Present for all notes

In attendance:

Meindert Boysen 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 Yates Project Manager, National Institute for Health and Care Excellence Present for all notes

Liga Kremere Administrator, National Present for note 1 to 26
Non-public attendees:

Ailsa Bosworth  Patient Expert  Present for notes 27 to 35
Peter Clark  Commissioning Expert  Present for notes 4 to 26
Adele Fielding  Clinical Expert  Present for notes 4 to 11
Dr Christopher Fox  Clinical Expert  Present for notes 15 to 23
Dr Chris Holroyd  Clinical Expert  Present for notes 27 to 35
Jennie Jones  Patient Expert  Present for notes 27 to 35
Chloe Pinder  Patient Expert  Present for notes 4 to 11
Professor Peter Taylor  Clinical Expert  Present for notes 27 to 35
Marcus Williams  Patient Expert  Present for notes 15 to 23
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 inotuzumab ozogamicin for treating relapsed or refractory B-cell acute lymphoblastic leukaemia, brentuximab vedotin for treating relapsed or refractory systemic anaplastic large cell lymphoma, baricitinib for moderate to severe rheumatoid arthritis and holoclar for treating limbal stem cell deficiency after eye burns.

2. The Chair informed the Committee of the non-public observers at this meeting: John Borrill, Kristina Dietz, Steve Estevao, Leslie Hayes, Lydia Shears, Ellise Warren

Any other business

3. None

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

Part 1 – Open session

4. The Chair welcomed the invited experts: Peter Clark, Edward Cox, Adele Fielding, Susan Griffin, Chloe Pinder and Ros Wade 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. Chair Professor Andrew Stevens, Professor Kathryn Abel, Mr Kamal Balakrishnan, Mr Michael Chambers, Mr David Chandler, Gail Coster, Dr Prithwiraj Das, Mr John P Hampson, Dr Nigel Langford, Dr Iain Miller, Professor Andrew Renehan, Dr Peter Selby, Professor Matt Stevenson, Dr Paul Tappenden, Mr Robert Walton, 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.

6.2. Professor Andrea Manca declared a personal non-specific financial interest as he has carried out paid consultancy for Pfizer by participating in an advisory board for a product in a different disease area. Professor Andrea Manca declared a personal non-specific financial interest co-applicant in the European Commission (EC) H2020 IMI2 funded project HARMONY. This is a public-private partnership and NOVARTIS is one of the participants for which Andrea’s organisation receives funding towards his salary.

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

6.2.2. Professor Stephen O’Brien declared a personal non-specific financial interest as his University and/or NHS Trust has received research funding for clinical trial work from the following companies: Pfizer, Novartis and Bristol-Myers Squibb.

6.2.3. It was agreed that this declaration would not prevent Professor Stephen O’Brien from participating in this section of the meeting.

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

6.4. 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.

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

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

7.2.1. It was agreed that this declaration would not prevent Adele Fielding from participating in this section of the meeting

8. The Chair introduced the lead team, John Hampson, Michael Chambers and David Chandele who gave presentations on the clinical effectiveness and cost effectiveness of inotuzumab ozogamicin for treating relapsed or refractory B-cell acute lymphoblastic leukaemia.
9. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.

10. 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.

11. 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**

12. Discussion on confidential information continued. This information was supplied by the company.

13. The Committee continued to discuss the clinical and cost effectiveness of inotuzumab ozogamicin for treating relapsed or refractory B-cell acute lymphoblastic leukaemia.

13.1. The committee decision was based on consensus.

14. The Committee instructed the technical team to prepare the Appraisal Consultation Document in line with their decisions.

**Appraisal of brentuximab vedotin for treating relapsed or refractory systemic anaplastic large cell lymphoma [ID512]**

**Part 1 – Open session**

15. The Chair welcomed the invited experts: Dwayne Boyers, Peter Clark, Moira Cruishank, Christopher Fox and Graham Scotland to the meeting and they introduced themselves to the Committee.

16. The Chair welcomed company representatives from Takeda UK to the meeting.

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

17.1. Chair Professor Andrew Stevens, Professor Kathryn Abel, Mr Kamal Balakrishnan, Mr David Chandler, Gail Coster, Dr Prithwiraj Das, Mr John P Hampson, Dr Nigel Langford, Dr Iain Miller, Professor Andrew Renehan, Dr Peter Selby, Professor Matt Stevenson, Dr Paul Tappenden, Mr Robert Walton, 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 brentuximab vedotin for treating relapsed or refractory systemic anaplastic large cell lymphoma.

17.2. Professor Andrea Manca declared a personal non-specific financial interest as co-applicant in the European Commission (EC) H2020 IMI2 funded project HARMONY. This is a public-private partnership and Takeda is one of the participants for which Andrea’s organisation receives funding towards his salary.

17.2.1. It was agreed that this declaration would not prevent Professor Andrea Manca from participating in this section of the meeting.
17.3. Professor Stephen O’Brien declared a personal non-specific financial interest as his university had previously received research funding for clinical trials from Ariad which was taken over by Takeda UK in February 2017.

17.3.1. It was agreed that this declaration would not prevent Professor Stephen O’Brien from participating in this section of the meeting.

17.4. Mr Michael Chambers declared a personal non-specific financial interest as he has participated in advisory boards for the IMI Get Real project, for which Takeda UK is a partner organisation.

17.4.1. It was agreed that this declaration would not prevent Mr Michael Chambers from participating in this section of the meeting.

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

18.1. 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 brentuximab vedotin for treating relapsed or refractory systemic anaplastic large cell lymphoma.

19. The Chair asked all other invited guests (ERG and invited experts, not including observers) to declare their 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 brentuximab vedotin for treating relapsed or refractory systemic anaplastic large cell lymphoma.

19.2. Dr Christopher Fox declared a personal non specific financial interest as he has presented and received payment for participating in advisory boards for Takeda.

19.2.1. It was agreed that this declaration would not prevent Dr Christopher Fox from participating in this section of the meeting.

20. The Chair introduced the lead team, Dr Robert Walton, Mr Iain Miller and Dr Judith Wardle who gave presentations on the clinical effectiveness and cost effectiveness of brentuximab vedotin for treating relapsed or refractory systemic anaplastic large cell lymphoma.

21. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.

22. 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.
23. 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**

24. Discussion on confidential information continued. This information was supplied by the company.

25. The Committee continued to discuss the clinical and cost effectiveness of brentuximab vedotin for treating relapsed or refractory systemic anaplastic large cell lymphoma.

25.1. The committee decision was based on consensus.

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

**Appraisal of baricitinib for moderate to severe rheumatoid arthritis [ID979]**

**Part 1 – Open session**

27. The Chair welcomed the invited experts: Ailsa Bosworth, Jennie Jones, Dr Chris Holroyd, Emma Simpson, Matt Stevenson, Professor Peter Taylor to the meeting and they introduced themselves to the Committee.

28. The Chair welcomed company representatives from Eli Lilly and Company Limited to the meeting.

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

29.1. Chair Professor Andrew Stevens, Professor Kathryn Abel, Mr Kamal Balakrishnan, Mr Michael Chambers, Mr David Chandler, Gail Coster, Dr Prithwiraj Das, Mr John P Hampson, Dr Nigel Langford, Professor Andrea Manca, Dr Iain Miller, Professor Andrew Renihan, Professor Stephen O’Brien, Dr Peter Selby, Dr Paul Tappenden, Mr Robert Walton, 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 baricitinib for moderate to severe rheumatoid arthritis.

29.2. It was noted that Committee member Professor Matt Stevenson is serving as an ERG representative and were therefore absent from the Committee.

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

30.1. 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 baricitinib for moderate to severe rheumatoid arthritis.

31. The Chair asked all other invited guests (ERG and invited experts, not including observers) to declare their relevant interests.
31.1. Jennie Jones 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 baricitinib for moderate to severe rheumatoid arthritis.

31.2. Ailsa Bosworth declared a personal non-specific financial interest as her organisation has received funding grants from the pharmaceutical industry.

31.2.1. It was agreed that this declaration would not prevent Ailsa Bosworth from participating in this section of the meeting.

31.3. Dr Chris Holroyd declared a personal non-specific financial interest as he has received funding from industry for lectures.

31.3.1. It was agreed that this declaration would not prevent Dr Chris Holroyd from participating in this section of the meeting.

31.4. Professor Peter Taylor declared a personal non-specific financial interest as he has received research grants from industry and funding for consultancy work.

31.4.1. It was agreed that this declaration would not prevent Professor Peter Taylor from participating in this section of the meeting.

32. The Chair introduced the lead team, David Chandler, Professor Stephen O’Brien and Professor Andrew Renehan who gave presentations on the clinical effectiveness and cost effectiveness of baricitinib for moderate to severe rheumatoid arthritis.

33. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.

34. 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.

35. 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**

36. Discussion on confidential information continued. This information was supplied by the company.

37. The Committee continued to discuss the clinical and cost effectiveness of baricitinib for moderate to severe rheumatoid arthritis.

37.1. The committee decision was based on consensus.

38. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.
Appraisal of holocular for treating limbal stem cell deficiency after eye burns
[ID899]

Part 1 – Open session

39. The Chair welcomed company representatives from Chiesi Ltd to the meeting.

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

40.1. Chair Professor Andrew Stevens, Professor Kathryn Abel, Mr Kamal Balakrishnan, Mr Michael Chambers, Mr David Chandler, Gail Coster, Dr Prithwiraj Das, Mr John P Hampson, Dr Nigel Langford, Professor Andrea Manca, Dr Iain Miller, Professor Andrew Renehan, Professor Stephen O’Brien, Dr Peter Selby, Professor Matt Stevenson, Dr Paul Tappenden, Mr Robert Walton, 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 holocular for treating limbal stem cell deficiency after eye burns.

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

41.1. 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 Holoclar for treating limbal stem cell deficiency after eye burns.

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

42.1. 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 Holoclar for treating limbal stem cell deficiency after eye burns.

43. 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.

44. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.

45. 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.

46. 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

47. Discussion on confidential information continued. This information was supplied by the company.

48. The Committee continued to discuss the clinical and cost effectiveness of Holoclар for treating limbal stem cell deficiency after eye burns

49. 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

50. Wednesday 14 June 2017 at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.