

Technology Appraisal Committee Meeting (Committee C)

Minutes: Confirmed

Date and Time: Thursday 16 March 2017, 10:00 to 16:30

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

Present:	1. Chair Professor Andrew Stevens 2. Professor Kathryn Abel 3. Mr Kamal Balakrishnan 4. Mr Michael Chambers 5. Mr David Chandler 6. Mrs Gail Coster 7. Dr Prithwiraj Das 8. Mr John P Hampson 9. Dr Nigel Langford 10. Professor Andrea Manca 11. Dr Iain Miller 12. Professor Eugene Milne 13. Professor Peter Selby 14. Professor Matt Stevenson 15. Dr Paul Tappenden 16. Robert Walton 17. Dr Judith Wardle	Present for all notes Present for notes 01 – 16 and 29 - 40 Present for all notes Present for all notes Present for all notes
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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
Cheryl Hinds	Administrator, National Institute for Health and Care Excellence	Present for all notes

Irina Voicechovskaja	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 01 – 16
Carl Prescott	Technical Adviser, National Institute for Health and Care Excellence	Present for notes 01 – 16
Neil Hewitt	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 17 - 28
Sally Doss	Technical Adviser, National Institute for Health and Care Excellence	Present for notes 17 – 28
Ross Dent	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 29 – 40
Nicola Hay	Technical Adviser, National Institute for Health and Care Excellence	Present for notes 29 – 40

Non-public attendees:

Dr Janette Greenhalgh	ERG representative	Present for notes 05 – 13
Rachel Houten	ERG representative	Present for notes 05 – 13
Professor Matt Stevenson	ERG representative	Present for notes 17 – 25
Professor James Mason	ERG representative	Present for notes 29 – 37
Dr Chidozie Nduka	ERG representative	Present for notes 29 – 37
Francisco C Figueiredo	Clinical Expert	Present for notes 05 – 13
Alex Shortt	Clinical Expert	Present for notes 05 – 13
Peter Clark	Commissioning Expert	Present for notes 17 – 25 and 29 – 37
Debbie Morrison	NICE observer	Present for notes 01 – 16
Marie Harrisinigh	NICE observer	Present for notes 17 – 28
Lee Walker	NICE observer	Present for all notes
Chris Eatough	NICE observer	Present for all notes
Steve Estevao	NICE observer	Present for all notes
Karyo Angeloudis	NICE observer	Present for all notes
Carl Boswell	NICE observer	Present for notes 29 – 40
Alex Filby	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 holoclar for treating limbal stem cell deficiency after eye burns, ponatinib for treating chronic myeloid leukaemia and acute lymphoblastic leukaemia and venetoclax for treating chronic lymphocytic leukaemia.
2. The Chair informed the Committee of the non-public observers at this meeting: Karyo Angeloudis, Carl Boswell, Chris Eatough, Steve Estevao, Alex Filby, Marie Harrisongh, Debbie Morrison and Lee Walker.
3. Apologies were received from Professor Stephen O'Brien and Professor Andrew Renahan.

Any other Business

4. None

Appraisal of holoclar for treating limbal stem cell deficiency after eye burns [ID899]

Part 1 – Open session

5. The Chair welcomed the invited experts: Francisco C Figueiredo, Dr Janette Greenhalgh, Rachel Houten and Alex Shortt to the meeting and they introduced themselves to the Committee.
6. The Chair welcomed company representatives from Chiesi Ltd to the meeting.
7. The Chair asked all Committee members to declare any relevant interests
 - 7.1. Professor Kathryn Abel, Mr Kamal Balakrishnan, Mr Michael Chambers, Mr David Chandler, Gail Coster, Dr Prithviraj Das, Mr John P Hampson, Dr Nigel Langford, Professor Andrea Manca, Dr Iain Miller, Professor Eugene Milne, Dr Peter Selby, Professor Matt Stevenson, Dr Paul Tappenden, Robert Walton 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 holoclar for treating limbal stem cell deficiency after eye burns.
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 holoclar for treating limbal stem cell deficiency after eye burns.

9. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.
 - 9.1. Francisco C Figueiredo, Dr Janette Greenhalgh and Rachel Houten 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.
 - 9.2. Alex Shortt declared a non-personal non-specific financial interest due to his involvement in a clinical programme capable of reproducing a similar technology to the one being appraised.
 - 9.2.1. It was agreed that this declaration would not prevent 9.2. Alex Shortt from participating in this section of the meeting
10. The Chair introduced the lead team, Professor Stephen O'Brien, Dr Paul Tappenden and Dr Judith Wardle who gave presentations on the clinical effectiveness and cost effectiveness of holoclar for treating limbal stem cell deficiency after eye burns.
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 holoclar for treating limbal stem cell deficiency after eye burns.
 - 15.1. The committee decision was based on consensus.
16. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.

Appraisal of ponatinib for treating chronic myeloid leukaemia and acute lymphoblastic leukaemia [ID671]

Part 1 – Open session

17. The Chair welcomed the invited experts: Professor Matt Stevenson and Peter Clark to the meeting and they introduced themselves to the Committee.

18. The Chair welcomed company representatives from Incyte Corporation to the meeting.
19. The Chair asked all Committee members to declare any relevant interests
 - 19.1. 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 Eugene Milne, Dr Peter Selby, Robert Walton 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 ponatinib for treating chronic myeloid leukaemia and acute lymphoblastic leukaemia.
 - 19.2. Professor Andrea Manca declared a non-personal specific financial interest as co-investigator in the EU IMI2 funded "HARMONY" project, which focuses on a number of haematological malignancies including ALL and CML.
 - 19.2.1 It was agreed that this declaration would not prevent Professor Andrea Manca from participating in this section of the meeting.
 - 19.3. Dr Paul Tappenden declared a non-personal specific financial interest he acted as an internal peer reviewer for the Evidence Review Group Report for this appraisal, but would not be named as an ERG member.
 - 19.3.1 It was agreed that this declaration would not prevent Dr Paul Tappenden from participating in this section of the meeting.
- 19.4. Professor Matt Stevenson is conflicted as his organisation is the Evidence Review Group for this appraisal
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 ponatinib for treating chronic myeloid leukaemia and acute lymphoblastic leukaemia.
21. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) 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 ponatinib for treating chronic myeloid leukaemia and acute lymphoblastic 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 ponatinib for treating chronic myeloid leukaemia and acute lymphoblastic leukaemia.
 - 27.1. The committee decision was based on consensus.
28. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

Appraisal of venetoclax for treating chronic lymphocytic leukaemia [ID944]

Part 1 – Open session

29. The Chair welcomed the invited experts: Peter Clark, Professor James Mason and Dr Chidozie Nduka to the meeting and they introduced themselves to the Committee.
30. The Chair welcomed company representatives from AbbVie to the meeting.
31. The Chair asked all Committee members to declare any relevant interests
 - 31.1. 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 Eugene Milne, Dr Peter Selby, Professor Matt Stevenson, Dr Paul Tappenden, Robert Walton 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 venetoclax for treating chronic lymphocytic leukaemia.

- 31.2. Professor Andrea Manca declared a non-personal specific financial interest as co-investigator in two research grants relating to CLL (a NIHR PGfAR project and the recently funded EU IMI2 “HARMONY” project).
 - 31.2.1. It was agreed that this declaration would not prevent Professor 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 venetoclax for treating chronic lymphocytic leukaemia.
33. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) 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 venetoclax for treating chronic lymphocytic 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 venetoclax for treating chronic lymphocytic 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. Wednesday 12 April 2017 10:00 – 17:00 at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.