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 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 Eugene Milne Present for all notes
13. Professor Peter Selby Present for all notes
14. Professor Matt Stevenson Present for all notes 01 – 16 and 29 - 40
15. Dr Paul Tappenden Present for all notes
16. Robert Walton Present for all notes
17. Dr Judith Wardle Present for all notes

In attendance:

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Notes</th>
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<tbody>
<tr>
<td>Meindert Boysen</td>
<td>Programme Director, National Institute for</td>
<td>Present for all notes</td>
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<td></td>
<td>Health and Care Excellence</td>
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<tr>
<td>Frances Sutcliffe</td>
<td>Associate Director, National Institute for</td>
<td>Present for all notes</td>
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<td>Health and Care Excellence</td>
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<tr>
<td>Stephanie Yates</td>
<td>Project Manager, National Institute for</td>
<td>Present for all notes</td>
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<td>Health and Care Excellence</td>
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<tr>
<td>Cheryl Hinds</td>
<td>Administrator, National Institute for Health</td>
<td>Present for all notes</td>
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<td></td>
<td>and Care Excellence</td>
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<tr>
<td>Name</td>
<td>Position</td>
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<tr>
<td>Irina Voicechovskaja</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>01 – 16</td>
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<tr>
<td>Carl Prescott</td>
<td>Technical Adviser, National Institute for Health and Care Excellence</td>
<td>01 – 16</td>
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<tr>
<td>Neil Hewitt</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>17 - 28</td>
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<tr>
<td>Sally Doss</td>
<td>Technical Adviser, National Institute for Health and Care Excellence</td>
<td>17 – 28</td>
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<tr>
<td>Ross Dent</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>29 – 40</td>
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<tr>
<td>Nicola Hay</td>
<td>Technical Adviser, National Institute for Health and Care Excellence</td>
<td>29 – 40</td>
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**Non-public attendees:**

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<thead>
<tr>
<th>Name</th>
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<th>Present for notes</th>
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<tr>
<td>Dr Janette Greenhalgh</td>
<td>ERG representative</td>
<td>05 – 13</td>
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<tr>
<td>Rachel Houten</td>
<td>ERG representative</td>
<td>05 – 13</td>
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<tr>
<td>Professor Matt Stevenson</td>
<td>ERG representative</td>
<td>17 – 25</td>
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<tr>
<td>Professor James Mason</td>
<td>ERG representative</td>
<td>29 – 37</td>
</tr>
<tr>
<td>Dr Chidozie Nduka</td>
<td>ERG representative</td>
<td>29 – 37</td>
</tr>
<tr>
<td>Francisco C Figueiredo</td>
<td>Clinical Expert</td>
<td>05 – 13</td>
</tr>
<tr>
<td>Alex Shortt</td>
<td>Clinical Expert</td>
<td>05 – 13</td>
</tr>
<tr>
<td>Peter Clark</td>
<td>Commissioning Expert</td>
<td>17 – 25</td>
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<td></td>
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<td>and 29 – 37</td>
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<tr>
<td>Debbie Morrison</td>
<td>NICE observer</td>
<td>01 – 16</td>
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<tr>
<td>Marie Harrisingh</td>
<td>NICE observer</td>
<td>17 – 28</td>
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<tr>
<td>Lee Walker</td>
<td>NICE observer</td>
<td>Present for all notes</td>
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<tr>
<td>Chris Eatough</td>
<td>NICE observer</td>
<td>Present for all notes</td>
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<tr>
<td>Steve Estevao</td>
<td>NICE observer</td>
<td>Present for all notes</td>
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<tr>
<td>Karyo Angeloudis</td>
<td>NICE observer</td>
<td>Present for all notes</td>
</tr>
<tr>
<td>Carl Boswell</td>
<td>NICE observer</td>
<td>29 – 40</td>
</tr>
<tr>
<td>Alex Filby</td>
<td>NICE observer</td>
<td>Present for all notes</td>
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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 Harrissingh, Debbie Morrison and Lee Walker.

3. Apologies were received from Professor Stephen O’Brien and Professor Andrew Renehan.

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 Prithviraj 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 Prithviraj 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.