Technology Appraisal Committee Meeting (Committee A)

Minutes: Confirmed

Date and Time: Thursday 2 November 2017, 10am – 5pm

Venue: Prospero House, 241 Borough High Street, London SE1 1GA

Present:
1. Chair, Dr Jane Adam Present for all notes
2. Vice Chair, Professor Iain Squire Present for all notes
3. Dr Jeremy Braybrooke Present for all notes
4. Dr Ian Bernstein Present for all notes
5. Dr Minal Bakhai Present for all notes
6. Dr Mohit Sharma Present for all notes
7. Dr John Watkins Present for all notes
8. Mr Stephen Sharp Present for all notes
9. Dr Rachel Hobson Present for all notes
10. Mr David Evans Present for all notes
11. Ms Pamela Rees Present for all notes
12. Dr Nery Woolacott Present for all notes
13. John Cairns Present for notes 1 to 22
14. Dr Paul Robinson Present for notes 11 to 47
15. Dr Justin Daniels Present for all notes

In attendance:

Meindert Boysen Programme Director, National Institute for Health and Care Excellence Present for all notes

Janet Robertson Associate Director, National Institute for Health and Care Excellence Present for all notes

Thomas Feist Project Manager, National Institute for Health and Care Excellence Present for all notes
<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Notes Present For</th>
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<tbody>
<tr>
<td>Jeremy Powell</td>
<td>Project Manager, National Institute for Health and Care Excellence</td>
<td>Present for all notes</td>
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<tr>
<td>Aminata Thiam</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>Present for notes 1 to 10</td>
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<tr>
<td>Joanna Richardson</td>
<td>Technical Adviser, National Institute for Health and Clinical Excellence</td>
<td>Present for notes 1 to 10</td>
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<tr>
<td>Anna Brett</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>Present for notes 11 to 22</td>
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<tr>
<td>Eleanor Donegan</td>
<td>Technical Adviser, National Institute for Health and Clinical Excellence</td>
<td>Present for notes 11 to 22</td>
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<tr>
<td>Zoe Charles</td>
<td>Technical Adviser, National Institute for Health and Clinical Excellence</td>
<td>Present for notes 23 to 47</td>
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<tr>
<td>Aimely Lee</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>Present for notes 23 to 34</td>
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<tr>
<td>Irina Voicechovskaja</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>Present for notes 35 to 47</td>
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**Evidence Review Group**

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Notes Present For</th>
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<tbody>
<tr>
<td>Steve Edwards</td>
<td>BMJ-TAG</td>
<td>Present for notes 1 to 10</td>
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<tr>
<td>Victoria Wakefield</td>
<td>BMJ-TAG</td>
<td>Present for notes 1 to 10</td>
</tr>
<tr>
<td>Peter Cain</td>
<td>BMJ-TAG</td>
<td>Present for notes 1 to 10</td>
</tr>
<tr>
<td>Adrian Bagust</td>
<td>Liverpool Reviews Implementation Group</td>
<td>Present for notes 11 to 19</td>
</tr>
<tr>
<td>Nigel Fleeman</td>
<td>Liverpool Reviews Implementation Group</td>
<td>Present for notes 11 to 19</td>
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<tr>
<td>Paul Tappenden</td>
<td>School of Health Related Research (SchARR)</td>
<td>Present for notes 23 to 31</td>
</tr>
<tr>
<td>Name</td>
<td>Organization</td>
<td>Notes Present</td>
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<tr>
<td>Jo Picot</td>
<td>Southampton Health Technology Assessment Centre</td>
<td>Present for notes 35 to 43</td>
</tr>
<tr>
<td>Keith Cooper</td>
<td>Southampton Health Technology Assessment Centre</td>
<td>Present for notes 35 to 43</td>
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<tr>
<td><strong>Experts</strong></td>
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<tr>
<td>Dr Kate Fife</td>
<td>Clinical expert, nominated by RCP</td>
<td>Present for notes 1 to 10</td>
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<tr>
<td>Dr Guy Faust</td>
<td>Clinical expert, nominated by MSD</td>
<td>Present for notes 1 to 10</td>
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<tr>
<td>Lindsey Devlin</td>
<td>Patient expert nominated by NET Foundation</td>
<td>Present for notes 1 to 10</td>
</tr>
<tr>
<td>Catherine Bouvier</td>
<td>Patient expert nominated by NET Foundation</td>
<td>Present for notes 1 to 10</td>
</tr>
<tr>
<td>Dr Marina Parton</td>
<td>Clinical expert, nominated by Eisai</td>
<td>Present for notes 11 to 19</td>
</tr>
<tr>
<td>Sally Greenbrook</td>
<td>Patient expert, Breast Cancer Now</td>
<td>Present for notes 11 to 19</td>
</tr>
<tr>
<td>Dr Daniel Rea</td>
<td>Clinical expert, nominated by RCP</td>
<td>Present for notes 35 to 43</td>
</tr>
<tr>
<td><strong>Non-public observers:</strong></td>
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<tr>
<td>Adam Storrow</td>
<td>NICE, Resource Impact Team</td>
<td>Present for notes all notes</td>
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<tr>
<td>Emily Crowe</td>
<td>NICE, Scientific Advice</td>
<td>Present for notes 1 to 10</td>
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<tr>
<td>Chloe Kastoryano</td>
<td>NICE Patient Involvement Adviser</td>
<td>Present for notes 1 to 22</td>
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<tr>
<td>Sunah Acktar</td>
<td></td>
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<tr>
<td>Maria Pitan</td>
<td>NICE, Corporate Office</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 Avelumab for treating metastatic merkel cell carcinoma [ID1102].

2. The Chair informed the Committee of the non-public observers at this meeting

3. Apologies were received from: Ms Ellen Rule, Dr Andrew England, Professor John McMurray, Dr Anne McCune, Dr Brian Shine, Mrs Sarah Parry, Dr Graham Ash, Professor Olivia Wu, Dr Rita Faria and Mr Adrian Griffin.

Appraisal of Avelumab for treating metastatic merkel cell carcinoma [ID1102].

Part 1 – Open session

4. The Chair welcomed the invited experts: Dr Kate Fife, Dr Guy Faust, Catherine Bouvier, Lindsey Devlin, Steve Edwards, Peter Cain and Victoria Wakefield to the meeting and they introduced themselves to the Committee.

5. The Chair welcomed company representatives from Merck to the meeting.

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

Dr Jane Adam, Professor Iain Squire, Dr Jeremy Braybrooke, Dr Ian Bernstein, Dr Minal Bakhai, Dr Mohit Sharma, Dr John Watkins, Mr Stephen Sharp, Dr Rachel Hobson, Mr David Evans, Ms Pamela Rees, Dr Nery Woolacott, John Cairns, Dr Justin Daniels 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 Avelumab for treating metastatic merkel cell carcinoma [ID1102].

1.1. Dr Paul Robinson was not present as his employer is involved in merkel cell research and may file for a license in the area.

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

2.1. 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 Avelumab for treating metastatic merkel cell carcinoma [ID1102].

3. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.
3.1. 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 Avelumab for treating metastatic merkel cell carcinoma [ID1102].

4. The Chair introduced the lead team, Dr John Watkins, Mr Stephen Sharp and Ms Pamela Rees, who gave presentations on the clinical effectiveness and cost effectiveness of Avelumab for treating metastatic merkel cell carcinoma [ID1102].

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

6. 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.

7. 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

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

9. The Committee continued to discuss the clinical and cost effectiveness of Avelumab for treating metastatic merkel cell carcinoma [ID1102].

9.1. The committee decision was based on consensus.

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

Appraisal of Eribulin for treating locally advanced or metastatic breast cancer after one prior chemotherapy regimen [ID1072]

Part 1 – Open session

11. The Chair welcomed the invited experts: Dr Marina Parton, Sally Greenbrook, Adrian Bagust and Nigel Fleeman to the meeting and they introduced themselves to the Committee.

12. The Chair welcomed company representatives from Eisai to the meeting.

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

13.1. Chair, Dr Jane Adam, Dr Jeremy Braybrooke, Dr Ian Bernstein, Dr Minal Bakhai, Dr Mohit Sharma, Dr John Watkins, Mr Stephen Sharp, Dr Rachel Hobson, Mr David Evans, Ms Pamela Rees, Dr Nery Woolacott, John Cairns, Dr Justin Daniels and Dr Paul Robinson 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 Eribulin for treating locally advanced or metastatic breast cancer after one prior chemotherapy regimen [ID1072].

13.2. Professor Iain Squire declared a personal non-specific financial interest as he has received honoraria from Novartis for participation in advisory boards and educational events relating to heart failure. His department is in receipt of financial support to fund research from Novartis. 13.2.1. It was agreed that this declaration would not prevent Professor Iain Squire from participating in this section of the meeting.

13.3. Dr Jeremy Braybrooke declared a personal non-specific financial interest as he had received honoraria in the field of breast cancer 2 years ago. 13.3.1. It was agreed that this declaration would not prevent Dr Jeremy Braybrooke from participating in this section of the meeting.

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

14.1. 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 Eribulin for treating locally advanced or metastatic breast cancer after one prior chemotherapy regimen [ID1072].

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

15.1. 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 Eribulin for treating locally advanced or metastatic breast cancer after one prior chemotherapy regimen [ID1072].

16. The Chair introduced the lead team, Dr Jane Adam, Dr Nerys Woolacott and Ms Pamela Rees who gave presentations on the clinical effectiveness and cost effectiveness of Eribulin for treating locally advanced or metastatic breast cancer after one prior chemotherapy regimen [ID1072].

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

18. 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.
19. 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**

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

21. The Committee continued to discuss the clinical and cost effectiveness of Eribulin for treating locally advanced or metastatic breast cancer after one prior chemotherapy regimen [ID1072].

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

**Appraisal of Ibrutinib for treating relapsed or refractory mantle cell lymphoma [ID753]**

**Part 1 – Open session**

23. The Chair welcomed the invited expert: Paul Tappenden to the meeting and he introduced himself to the Committee.

24. The Chair welcomed company representatives from Janssen to the meeting.

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

25.1. Chair, Dr Jane Adam, Dr Jeremy Braybrooke, Dr Ian Bernstein, Dr Minal Bakhai, Dr Mohit Sharma, Dr John Watkins, Mr Stephen Sharp, Dr Rachel Hobson, Mr David Evans, Ms Pamela Rees, Dr Nery Woolacott, Dr Justin Daniels and Dr Paul Robinson 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 Ibrutinib for treating relapsed or refractory mantle cell lymphoma [ID753].

25.2. Professor Iain Squire declared a personal non-specific - financial interest as he has received honoraria from Novartis for participation in advisory boards and educational events relating to heart failure. His department is in receipt of financial support to fund research from Novartis.  
25.2.1. It was agreed that this declaration would not prevent Professor Iain Squire from participating in this section of the meeting.

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

26.1. 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 Ibrutinib for treating relapsed or refractory mantle cell lymphoma [ID753].

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

27.1. 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 Ibrutinib for treating relapsed or refractory mantle cell lymphoma [ID753].

28. 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.

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

30. 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.

31. 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

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

33. The Committee continued to discuss the clinical and cost effectiveness of Ibrutinib for treating relapsed or refractory mantle cell lymphoma [ID753].

34. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

Appraisal of Fulvestrant for untreated locally advanced or metastatic oestrogen-receptor positive breast cancer [ID951]

Part 1 – Open session

35. The Chair welcomed the invited experts: Dr Daniel Rea, Jo Picot and Keith Cooper to the meeting and they introduced themselves to the Committee.

36. The Chair welcomed company representatives from AstraZeneca to the meeting.

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

37.1. Chair, Dr Jane Adam, Dr Jeremy Braybrooke, Dr Ian Bernstein, Dr Minal Bakhai, Dr Mohit Sharma, Dr John Watkins, Mr Stephen Sharp, Dr Rachel Hobson, Mr David Evans, Ms Pamela Rees, Dr Nery Woolacott,
Dr Justin Daniels and Dr Paul Robinson 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 Fulvestrant for untreated locally advanced or metastatic oestrogen-receptor positive breast cancer [ID951].

37.2. Professor Iain Squire declared a personal non-specific financial interest as he has received honoraria from Novartis for participation in advisory boards and educational events relating to heart failure. His department is in receipt of financial support to fund research from Novartis. 37.2.1. It was agreed that this declaration would not prevent Professor Iain Squire from participating in this section of the meeting.

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

38.1. 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 Fulvestrant for untreated locally advanced or metastatic oestrogen-receptor positive breast cancer [ID951].

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

39.1. 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 Fulvestrant for untreated locally advanced or metastatic oestrogen-receptor positive breast cancer [ID951].

40. 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.

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

42. 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.

43. 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
44. Discussion on confidential information continued. This information was supplied by the company.

45. The Committee continued to discuss the clinical and cost effectiveness of Fulvestrant for untreated locally advanced or metastatic oestrogen-receptor positive breast cancer [ID951]

46. 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

47. Tuesday 5 December 2017 at Prospero House 241 Borough High Street, SE1 1GA London.