

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

Jeremy Powell	Project Manager, National Institute for Health and Care Excellence	Present for all notes
Aminata Thiam	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 1 to 10
Joanna Richardson	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 1 to 10
Anna Brett	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 11 to 22
Eleanor Donegan	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 11 to 22
Zoe Charles	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 23 to 47
Aimely Lee	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 23 to 34
Irina Voicechovskaja	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 35 to 47
Evidence Review Group		
Steve Edwards	BMJ-TAG	Present for notes 1 to 10
Victoria Wakefield	BMJ-TAG	Present for notes 1 to 10
Peter Cain	BMJ-TAG	Present for notes 1 to 10
Adrian Bagust	Liverpool Reviews Implementation Group	Present for notes 11 to 19
Nigel Fleeman	Liverpool Reviews Implementation Group	Present for notes 11 to 19
Paul Tappenden	School of Health Related Research (ScHARR)	Present for notes 23 to 31

Jo Picot	Southampton Health Technology Assessment Centre	Present for notes 35 to 43
Keith Cooper	Southampton Health Technology Assessment Centre	Present for notes 35 to 43

Experts

Dr Kate Fife	Clinical expert, nominated by RCP	Present for notes 1 to 10
Dr Guy Faust	Clinical expert, nominated by MSD	Present for notes 1 to 10
Lindsey Devlin	Patient expert nominated by NET Foundation	Present for notes 1 to 10
Catherine Bouvier	Patient expert, nominated by NET Foundation	Present for notes 1 to 10
Dr Marina Parton	Clinical expert, nominated by Eisai	Present for notes 11 to 19
Sally Greenbrook	Patient expert, Breast Cancer Now	Present for notes 11 to 19
Dr Daniel Rea	Clinical expert, nominated by RCP	Present for notes 35 to 43

Non-public observers:

Adam Storrow	NICE, Resource Impact Team	Present for notes all notes
Emily Crowe	NICE, Scientific Advice	Present for notes 1 to 10
Chloe Kastoryano	NICE Patient Involvement Adviser	Present for notes 1 to 22
Sunah Acktar Maria Pitan	NICE, Corporate Office	

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.