

Technology Appraisal Committee Meeting (Committee [A])

Minutes: Confirmed

Date and Time: 20 September 2016, 10am – 4.30pm

Venue: Prospero House
24 High Street
SE1 7DA

Present:	1.	Dr Jane Adam	Present for all notes
	2.	Professor Iain Squire	Present for notes 1 to 16 and 17-25 only
	3.	Dr Graham Ash	Present for all notes
	4.	Dr Ian Bernstein	Present for all notes
	5.	Dr Jeremy Braybrooke	Present for notes 1 to 16 and 29 to 40
	6.	Dr Justin Daniels	Present for all notes
	7.	Mr Adrian Griffin	Present for notes 17 to 25
	8.	Dr Rachel Hobson	Present for all notes
	9.	Dr Anne McCune	Present for all notes
	10.	Dr Rita Faria	Present for all notes
	11.	Mrs Sarah Parry	Present for all notes
	12.	Miss Pamela Rees	Present for all notes
	13.	Dr Paul Robinson	Present for all notes
	14.	Dr Brian Shine	Present for all notes
	15.	Mr David Thomson	Present for all notes
	14.	Professor Olivia Wu	Present for all notes
	15.	Dr Nerys Woolacott	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
Liv Gualda	Project Manager, National Institute for Health and Care Excellence	Present for all notes

Marcia Miller	Technology Administrator, National Institute for Health and Care Excellence	Present for all notes
Henry Edwards	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 1 to 16
Zoe Charles	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 1 to 16
Boglarka Mikudina	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 17 to 29
Eleanor Donegan	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes for 17 to 29

Non-public observers:

Chloe Kastoranyo	NICE, PIP	Present for notes all notes
Leeza Osipenko	NICE, Scientific Advise	Present for notes 1 to 16
Rachel	LRiG, ERG team member	Present for all notes 17 - 25
Joshua South	NICE, Corporate office	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 Ibrutinib for treating Waldenström's macroglobulinaemia.
2. The Chair informed the Committee of the non-public observers at this meeting: Chloe Kastoryano, Leeza Osipenko and Joshua South.
3. Apologies were received from Professor John McMurray, Dr Mohit Misra, Mr Stephen Sharp, Ms Ellen Rule and Dr John Watkins

Notes from the last meeting

4. Minutes of the last meeting were agreed

Part 1 – Open session

5. The Chair welcomed the invited experts: Dr Shirley D'SA, Mr Mark Barnett, Mr Roger Brown and Dr Roger Owen, Paul Tappenden and **Praveen Thokala** to the meeting and they introduced themselves to the Committee.
6. The Chair welcomed company representatives from Janssen to the meeting.
7. The Chair asked all Committee members to declare any relevant interests
 - 7.1. **Dr Jane Adam, Professor Iain Squire, Dr Ian Bernstein, Dr Jeremy Braybrooke, Dr Justin Daniels, Dr Rachel Hobson, Dr Anne McCune, Dr Rita Faria, Mrs Sarah Parry, Miss Pamela Rees, Dr Paul Robinson, Dr Brian Shine, Mr David Thomson, Professor Olivia Wu and Dr Nerys Woolacott** 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 Waldenström's macroglobulinaemia
 - 7.2. Dr Graham Ash declared a non-personal specific financial interests as he is an investigator in a study sponsored by Janssen in a different disease area than the technology being discussed at this meeting.
 - 9.2.1 It was agreed that this declaration would not prevent Dr Graham Ash from participating in this section of the meeting.
 - 7.3. Mr Adrian Griffin declared a personal specific financial interest as Janssen is owned by his employers Johnson and Johnson.
 - 9.3.1 It was agreed that this declaration would prevent Mr Adrian Griffin from participating in the appraisal and he remained absent from the meeting
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 Ibrutinib for treating Waldenström's macroglobulinaemia [ID884]
9. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.
 - 9.1. Mr Mark Barnett, Mr Roger Brown, Paul Tappenden and Praveen Thokala 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 Waldenström's macroglobulinaemia.

9.2. Dr Roger Owen declared a personal specific financial interest as has carried out consultancy and advisory roles for Janssen. He has received support and to attend meetings.

9.3.1 It was agreed that this declaration would not prevent Dr Roger Owen from participating in the appraisal and he remained absent from the meeting

10. The Chair introduced the lead team, Dr Rachel Hobson, Dr Brian Shine and Ms Pamela Rees who gave presentations on the clinical effectiveness and cost effectiveness of Ibrutinib for treating Waldenström's macroglobulinaemia.
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 Ibrutinib for treating Waldenström's macroglobulinaemia [ID884]
16. 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 two or more prior chemotherapy regimens [ID964]

Part 1 – Open session

17. The Chair welcomed the invited experts: Dr Adrian Bagust, Nigel Fleeman, Dr Anne Rigg, and Mrs Sally Greenbrook to the meeting and they introduced themselves to the Committee.
18. The Chair welcomed company representatives from Eisai to the meeting.
19. The Chair asked all Committee members to declare any relevant interests
 - 19.1. **Dr Jane Adam, Professor Iain Squire, Dr Graham Ash, Dr Ian Bernstein, Dr Justin Daniels, Mr Adrian Griffin, Dr Rachel Hobson, Dr Anne McCune, Dr Rita Faria, Mrs Sarah Parry, Miss Pamela Rees, Dr Paul Robinson, Dr Brian Shine, Mr David Thomson, Professor Olivia Wu and Dr Nerys Woolacott** 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 two or more prior chemotherapy regimens [ID964]
 - 19.2. Dr Jeremy Braybrooke declared a personal specific financial interest as he has **previously talked at an Eisai staff training meeting on breast cancer.**
 - 9.2.1 It was agreed that this declaration would prevent Dr Jeremy Braybrooke from participating in the appraisal and he remained absent from the meeting.
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 **eribulin for treating locally advanced or metastatic breast cancer after two or more prior chemotherapy regimens.**
21. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.
 - 21.1. Adrian Bagust, Ms Sally Greenbrook and Nigel Fleeman 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 two or more prior chemotherapy regimens

- 21.2. Dr Anna Rigg declared a personal non specific financial interest as she has received **honoraria for speaking at academic meetings: Amgen, Astra Zeneca, Eisai, Novartis, Roche**
- 21.3. **Honoraria for advisory boards: Eisai, Roche, Celgene, Genomic Health and honorarium for being on steering committee for First Thoughts Meeting annually: Eisai**
- 21.3.1. It was agreed that this declaration would not prevent Dr Anna Rigg from participating in this section of the meeting.
22. The Chair introduced the lead team, Mr Andrew England, Mr Adrian Griffin and Mr David Thomson who gave presentations on the clinical effectiveness and cost effectiveness of **eribulin for treating locally advanced or metastatic breast cancer after two or more prior chemotherapy regimen.**
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 **eribulin for treating locally advanced or metastatic breast cancer after two or more prior chemotherapy regimens.**
28. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

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

Part 1 – Open session

29. The Chair welcomed the invited experts: Paul Tappenden to the meeting and they introduced themselves to the Committee.

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

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

31.1. **Dr Jane Adam, Professor Iain Squire, Dr Graham Ash, Dr Ian Bernstein, Dr Jeremy Braybrooke, Dr Justin Daniels, Dr Rachel Hobson, Dr Anne McCune, Dr Rita Faria, Mrs Sarah Parry, Miss Pamela Rees, Dr Paul Robinson, Dr Brian Shine, Mr David Thomson, Professor Olivia Wu and Dr Nerys Woolacott** 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**.

31.2. Mr Adrian Griffin declared a personal specific financial interest as Janssen is owned by his employers Johnson and Johnson.

9.2.1 It was agreed that this declaration would prevent Mr Adrian Griffin from participating in the appraisal and he remained absent from 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 **Ibrutinib for treating relapsed or refractory mantle cell lymphoma**.

33. The Chair asked all other invited guests (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 **Ibrutinib for treating relapsed or refractory mantle cell lymphoma**.

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 **Ibrutinib for treating relapsed or refractory mantle cell lymphoma.**
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. 15 November 2016, 10am at Prospero House, 241 Borough High Street, London SE1 1GA