

Technology Appraisal Committee Meeting (Committee A)

Minutes: Confirmed

Date and Time: 29th September 2015

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

Present:	1. Dr Jane Adam 2. Professor Iain Squire 3. Brian Shine 4. Professor John McMurray 5. Dr Anne McCune 6. Dr Jeremy Braybrooke 7. Dr Gerardine Bryant 8. Professor Olivia Wu 9. Dr John Watkins 10. Mr David Thomson 11. Ms Pamela Rees 12. Dr Andrew England 13. Mr Adrian Griffin 14. Dr Mohit Misra 15. Dr Eldon Spackman 16. Dr Nerys Woolacott 17. Mr Stephen Sharp	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
Janet Robertson	Associate Director, National Institute for Health and Care Excellence	Present for all notes
Bijal Joshi	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
Christian Griffiths	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 1 to 17
Joanna Richardson	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 1 to 17

Ahmed Elsada	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 18 to 29
Zoe Charles	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 18 to 29
<u>ERG</u>		
Dr Bram Ramakers	Systematic Reviewer, Kleijnen Systematic Reviews	Present for notes 1 to 17
Robert Wolff	Researcher, Kleijnen Systematic Reviews	Present for notes 1 to 17
<u>Clinical Expert</u>		
Dr Simon Rule	Consultant Haematologist / Professor of Clinical Haematology nominated by Janssen and Royal College of Physicians	Present for notes 1 to 17
<u>Patient Expert</u>		
Mrs Katharine Robinson	Patient expert nominated by Lymphoma Association	Present for notes 1 to 17
<u>Non-public observers:</u>		
Kate Moore	NICE	
Chloe Kastoryano	NICE	Present for notes all notes Present for all notes 1 to 17

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 bortezomib for previously untreated mantle cell lymphoma [ID724].
2. The Chair informed the Committee of the non-public observers at this meeting: Kate Moore and Chloe Kastoryano
3. Apologies were received from Dr Graham Ash, Professor Aileen Clarke, Mrs Sarah Parry, Dr Paul Robinson and Ellen Rule.

Notes from the last meeting

4. Minutes of the last meeting were agreed.

Appraisal of bortezomib for previously untreated mantle cell lymphoma [ID724]

Part 1 – Open session

5. The Chair welcomed the invited experts and ERG: Professor Simon Rule, Mrs Katherine Robinson, Dr Bram Raemakers and Dr Robert Wolff 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 Brian Shine
Professor John McMurray, Dr Anne McCune, Dr Jeremy Braybrooke
Dr Geraradine Bryant, Professor Olivia Wu, Dr John Watkins
Mr David Thomson, Miss Pamela Rees, Dr Andrew England
Mr Adrian Griffin, Dr Mohit Misra, Dr Nerys Woolacott, Mr Stephen Sharp 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 Bortezomib for previously untreated mantle cell lymphoma.
 - 7.2. Dr Jeremy Braybrooke declared a personal specific interest as he is a co-investigator on clinical trials in breast cancer
9.2.1 It was agreed that this declaration would not prevent Dr Jeremy Braybrooke from participating in this section of the meeting.
 - 7.3. Dr Eldon Spackman declared a non-personal specific financial interest as he participated in a conference sponsored by Pfizer. This was in a different disease area.
9.3.1 It was agreed that this declaration would not prevent Dr Eldon Spackman from participating in this section of the meeting.
 - 7.4. Mr Adrian Griffin declared a personal interest as his company have rights to the technology being discussed. It was agreed that this declaration would prevent Mr Adrian Griffin from participating in the appraisal and he was 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 bortezomib for previously untreated mantle cell lymphoma.
9. The Chair asked all other invited guests assessment group/ERG and invited experts, not including observers) to declare their relevant interests.
 - 9.1. Mrs Katherine Robinson, Dr Bram Raemakers and Dr Robert Wolff 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 Bortezomib for previously untreated mantle cell lymphoma.
 - 9.2. Dr Simon Rule declared a personal non- specific financial interest as he received payment for giving lectures and attendance at advisory boards for Janssen
9.2.1. It was agreed that this declaration would not prevent Dr Simon Rule from participating in this section of the meeting
10. The Chair introduced the lead team, Dr Brian Shine, Mr David Thompson who gave presentations on the clinical effectiveness and cost effectiveness of **bortezomib for previously untreated mantle cell lymphoma**.

11. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of **bortezomib for previously untreated mantle cell lymphoma**. on the basis of the evidence before them, and potential equality issues raised in this appraisal. They sought clarification and advice from the experts present. The discussions included:
 - 11.1. The patient experience of people with mantle cell lymphoma
 - 11.2. The current treatment pathway for mantle cell lymphoma
 - 11.3. The design and the results of the pivotal trial, LYM-3002
 - 11.4. The generalisability of LYM-3002 to people in the NHS with mantle cell lymphoma
 - 11.5. The results of the indirect comparison comparing bortezomib with R-FC and R-bendamustine
 - 11.6. Adverse effects and mode of administration of bortezomib
 - 11.7. The inputs of the health economic model that had been presented by the company
 - 11.8. The ERG's exploratory analyses
 - 11.9. The plausibility of the assumptions used by the company and the ERG
12. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
13. 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.
14. The Chair then thanked the experts, company representatives and academic group for their attendance, participation and contribution to the appraisal and they left the meeting.

Part 2 – Closed session

15. Discussion on confidential information continued. This information was supplied by the company.
16. The Committee continued to discuss the clinical and cost effectiveness of **bortezomib for previously untreated mantle cell lymphoma**.
17. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

Appraisal of trastuzumab emtansine for treating HER2-positive, unresectable locally advanced or metastatic breast cancer after treatment with trastuzumab and a taxane

Part 1 – Open session

18. The Chair welcomed company representatives from Roche to the meeting.
19. The Chair asked all Committee members to declare any relevant interests
 - 19.19. Dr Jane Adam, Professor Iain Squire, Dr Brian Shine
Professor John McMurray, Dr Anne McCune ,
Dr Gerardine Bryant, Professor Olivia Wu, Dr John Watkins
Mr David Thomson, Miss Pamela Rees, Dr Andrew England Mr Adrian Griffin,
Dr Mohit Misra, Dr Nerys Woolacott, Mr Stephen Sharp 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 **trastuzumab emtansine for treating HER2-positive, unresectable locally advanced or metastatic breast cancer after treatment with trastuzumab and a taxane**

- 19.20. Dr Jeremy Braybrooke declared a non-personal specific financial interest as he is a co-investigator on clinical trials in breast cancer
 - 9.2.1 It was agreed that this declaration would prevent him from participating in this section of the meeting and he was absent.
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 Trastuzumab emtansine for treating HER2-positive, unresectable locally advanced or metastatic breast cancer after treatment with trastuzumab and a taxane declared a personal non-specific financial interest as he holds shares in healthcare industries but not for any of the manufacturer for this appraisal.
 - 20.2. 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 Trastuzumab emtansine for treating HER2-positive, unresectable locally advanced or metastatic breast cancer after treatment with trastuzumab and a taxane.
21. The Committee discussed the outcome of the appeal against the Final Appraisal Determination for this appraisal. The discussions included:
 - 19.21. NICE's position statement about the relevance of the 2014 PPRS to assessing the cost effectiveness of new branded medicines, and what this meant for the Committee's consideration of cost effectiveness.
 - 19.22. Whether the PPRS could potentially be relevant to assessing opportunity costs that underlie a NICE appraisal.
 - 19.23. The company's proposal to take the 2014 PPRS into account in this appraisal.
22. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
23. 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.
24. The Chair then thanked the experts, company representatives and academic group for their attendance, participation and contribution to the appraisal and they left the meeting.

Part 2 – Closed session

25. The Committee continued to discuss the clinical and cost effectiveness of trastuzumab emtansine for treating HER2-positive, unresectable locally advanced or metastatic breast cancer after treatment with trastuzumab and a taxane
26. 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

27. Tuesday 27th October 2015, at Prospero House, 241 Borough High Street, London SE1 1GA