Technology Appraisal Committee Meeting (Committee [A])

Minutes: [Confirmed]

Date and Time: Thursday 8 June 2017, 10am

Venue: NICE London Office
Prince of Wales Suite 10 Spring Gardens SW1A 2BU

Present:
1. Chair Jane Adam Present for all notes
2. Professor Iain Squire Present for all notes
3. Dr Graham Ash Present for all notes
4. Dr Jeremy Braybrooke Present for all notes
5. Mr John Cairns Present for all notes
6. Dr Justin Daniels Present for all notes
7. Dr Andrew England Present for all notes
8. Mr David Evans Present for notes 17 to 25
9. Dr Rita Faria Present for all notes
10. Mr Adrian Griffin Present for all notes
11. Dr Mohit Misra Present for all notes
12. Dr Mohit Sharma Present for all notes
13. Dr Ian Bernstein Present for all notes
14. Mrs Sarah Parry Present for all notes
15. Dr Paul Robinson Present for all notes
16. Dr Brian Shine Present for all notes

In attendance:

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

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

Jeremy Powell Project Manager, Present for all notes
Project Manager,
National Institute for
Health and Care
Excellence
<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Notes Present For</th>
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<tbody>
<tr>
<td>Marcia Miller</td>
<td>Technology Appraisal Administrator, National Institute for Health and Care Excellence</td>
<td>Present for all notes</td>
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<tr>
<td>Anwar Jilani</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>Present for notes xx to xx</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 xx to xx</td>
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<tr>
<td>Sana Khan</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>Present for notes 8 to 16</td>
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<td>Hamish Lungaria</td>
<td>Technical Analyst, National Institute for Health and Clinical Excellence</td>
<td>Present for notes xx to xx</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 xx to xx</td>
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<tr>
<td>Keith Cooper</td>
<td>Southampton Technology Assessment, University of Southampton</td>
<td>Present for notes xx to xx</td>
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<tr>
<td>Jo Lord</td>
<td>Southampton Technology Assessment University of Southampton</td>
<td>Present for notes xx to xx</td>
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<tr>
<td>Angela Stainthorpe</td>
<td>Liverpool Reviews and Implementation Group, LRiG</td>
<td>Present for notes 17 to 26</td>
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<tr>
<td>Rumona Dickson</td>
<td>Liverpool Reviews and Implementation Group, LRiG</td>
<td>Present for notes 17 to 26</td>
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<tr>
<td>Rob Riemsma</td>
<td>Kleijnen Systematic Reviews</td>
<td>Present for 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 Reslizumab for treating eosinophilic asthma inadequately controlled on inhaled corticosteroids [ID872]

2. The Chair informed the Committee of the non-public observers at this meeting: Joshua South, Chloe Kastoryano Jane Lynn,

3. Apologies were received from Dr Rachel Hobson, Dr Anne McCune, Professor John McMurray, Professor Oliva Wu, Dr Nerys Woolacott, Ms Ellen Rule, Mr Stephen Sharp and Ms Pamela Rees

**Notes from the last meeting**

4. The minutes from the last meeting were agreed.

**Appraisal of Reslizumab for treating eosinophilic asthma inadequately controlled on inhaled corticosteroids**

**Part 1 – Open session**

5. The Chair welcomed the invited experts: Keith Cooper and Jo Lord to the meeting and they introduced themselves to the Committee.

6. The Chair welcomed company representatives from Teva to the meeting.

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

7.1. Dr Jane Adam, Dr Graham Ash, Dr Jeremy Braybooke, Mr John Cairns, Dr Justin Daniels, Mr Andrew England, Mr David Evans, Dr Rita Faria, Mr Adrian Griffin, Dr Mohit Misra, Dr Mohit Sharma, Dr Ian Bernstein, Mrs Sarah Parry, Dr Paul Robinson and Dr Brian Shine 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 Reslizumab for treating eosinophilic asthma inadequately controlled on inhaled corticosteroids

7.2. Professor Iain Squire declared a personal non-specific financial interest as he has received honoraria from Novartis and support for research in cardiovascular disease.

9.2.1 It was agreed that this declaration would not prevent Professor Iain Squire from participating in this section of 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 Reslizumab for treating eosinophilic asthma inadequately controlled on inhaled corticosteroids.

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

9.1. 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 Reslizumab for treating eosinophilic asthma inadequately controlled on inhaled corticosteroids.

10. 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.

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 Reslizumab for treating eosinophilic asthma inadequately controlled on inhaled corticosteroids.

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

**Appraisal of Palbociclib in combination with an aromatase inhibitor for previously untreated metastatic, hormone receptor-positive, HER2-negative breast cancer [ID915]**

**Part 1 – Open session**

17. The Chair welcomed the invited experts: Dr Nicholas Turner, Melanie Sturtevant to the meeting and they introduced themselves to the Committee.

18. The Chair welcomed company representatives from Pfizer to the meeting.

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

19.1. Dr Jane Adam, Dr Graham Ash, Dr Jeremy Braybrooke, Mr John Cairns, Dr Justin Daniels, Mr Andrew England, Mr David Evans, Dr Rita Faria, Mr Adrian Griffin, Dr Mohit Misra, Dr Mohit Sharma, Dr Ian Bernstein, Mrs Sarah Parry, Dr Paul Robinson and Dr Brian Shine 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 Palbociclib in combination with an aromatase inhibitor for previously untreated metastatic, hormone receptor-positive, HER2-negative breast cancer.

19.2. Professor Iain Squire declared a personal non-specific financial interest as he has received honoraria from Novartis and support for research in cardiovascular disease.

9.2.1 It was agreed that this declaration would not prevent Professor Iain Squire from participating in this section of the meeting.

19.3. Mr David Evans declared a personal specific financial interest as he holds shares in the comparator company AstraZeneca.

9.3.1 It was agreed that this declaration would prevent Mr David Evans from participating in this section of the meeting and he observed Part 1 of the meeting only.

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 Palbociclib in combination with an aromatase inhibitor for previously untreated metastatic, hormone receptor-positive, HER2-negative breast cancer.
The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.

21. Angela Stainthorpe, Rumona Dickson 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 Palbociclib in combination with an aromatase inhibitor for previously untreated metastatic, hormone receptor-positive, HER2-negative breast cancer.

21.1. Dr Nicholas Turner declared a personal specific pecuniary interest as he has sat on advisory boards and received honoraria and research funding from Pfizer

21.1.1. It was agreed that this declaration would not prevent Dr Nicholas Turner from participating in the meeting.

21.2. Melanie Sturtevant declared a personal specific pecuniary interest as her employer Breast Cancer Now receives funding from Pfizer for its catalyst research programme this is separate/independent to their policy and campaign work.

21.2.1. It was agreed that this declaration would not prevent Dr Nicholas Turner from participating in the meeting.

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 Palbociclib in combination with an aromatase inhibitor for previously untreated metastatic, hormone receptor-positive, HER2-negative breast cancer.

28. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.
Appraisal of Naltrexone-bupropion (prolonged-release) for managing overweight and obesity (ID757)

Part 1 – Open session

29. The Chair welcomed the invited experts: Dr Barbara McGowan, Rob Riemsma and Sabine Grimme to the meeting and they introduced themselves to the Committee.

30. The Chair welcomed company representatives from Orexigen Therapeutics to the meeting.

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

19.1. Dr Jane Adam, Dr Graham Ash, Dr Jeremy Braybooke, Mr John Cairns, Dr Justin Daniels, Mr Andrew England, Mr David Evans, Dr Rita Faria, Mr Adrian Griffin, Dr Mohit Misra, Dr Mohit Sharma, Dr Ian Bernstein, Mrs Sarah Parry, Dr Paul Robinson and Dr Brian Shine 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 Naltrexone-bupropion (prolonged-release) for managing overweight and obesity.

19.2. Professor Iain Squire declared a personal non-specific financial interest as he has received honorarium from Novartis and support for research in cardiovascular.

19.2.1 It was agreed that this declaration would not prevent Professor Iain Squire from participating in this section of the meeting

19.3. Mr David Evans declared a personal specific financial interest as he holds shares in the comparator company AstraZeneca.

19.3.1 It was agreed that this declaration would prevent Mr David Evans from participating in this section of the meeting and 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 Naltrexone-bupropion (prolonged-release) for managing overweight and obesity (ID757)

21. The Chair asked all other invited guests the ERG and invited experts, not including observers, to declare their relevant interests.
21.1. Rob Riemsma and Sabine Grimm 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 Naltrexone-bupropion (prolonged-release) for managing overweight and obesity.

Dr Barbara McGowan declared a personal specific pecuniary interest as she has participated in pharmaceuticals advisory meetings including for Orexigian in the past Clinical Lead and Principal Investigator for commercial and clinical trials in obesity.

28.1.1. It was agreed that this declaration would not prevent Dr Barbara McGowan from participating in the meeting.

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

28. The Committee instructed the technical team to prepare the [Appraisal Consultation Document (ACD) or Final Appraisal Determination (FAD)] in line with their decisions.

Date, time and venue of the next meeting

29. Tuesday 8 August 2017, 10am at NICE London Office, Prince of Wales Suite 10 Spring Gardens SW1A 2BU