

## Technology Appraisal Committee Meeting (Committee A)

**Minutes:** Confirmed

**Date and Time:** 4 October 2017

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

<b>Present:</b>	1. Chair Dr Jane Adam 2. Vice Chair, Professor Iain Squire 3. Dr Jeremy Braybrooke 4. Dr Justin Daniels 5. Mr Adrian Griffin 6. Professor John McMurray 7. Dr Minal Bakhai 8. Mrs Sarah Parry 9. Ms Pamela Rees 10. Dr Brian Shine 11. Mr David Evans 12. Dr John Watkins 13. Professor Olivia Wu 14. Dr Nerys Woolacott 15. Dr Rita Faria 16. Dr Paul Robinson 17. Dr Ian Bernstein	Present for all notes Present for notes 1 to 20 Present for all notes Present for notes 1 to 20 Present for notes 21 to 30
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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
Thomas Feist	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
Anwar Jilani	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 1-16
Marcela Haasova	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 17-27
Joanna Richardson	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 1-27
Eleanor Donegan	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 28-37
Irina Voicechovskaja	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 28-37
<b>Evidence Review Group</b>		
Rumona Dickson	Liverpool reviews and Implementation group	Present for notes 1-13
Angela Stainthorpe	Liverpool reviews and implementation group	Present for notes 1-13
Nasuh Buyukkaramikli	Health Economist Kleijnen Systematic Reviews	Present for notes 17-25
<b>Decision Support Unit</b>		
Becky Pennington	Decision Support Unit	Present for notes 17-25
<b>Experts</b>		
Dr Alistair Ring	Clinical expert nominated by nominated by RCP	Present for notes 1-13

Melanie Sturtevant	Patient expert nominated by Breast Cancer Now	Present for notes 1-13
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**Non-public observers:**

Linda Grainger	NICE, Appraisal Editor	Present for all notes
Jonathan Littler	NICE, Corporate Office	Present for all notes
Anwar Jilani	TA, Technical Analyst	Present for notes 1 to 16
Becky Pennington	Decision Support Unit	Present notes 1 to 16
Louise Fletcher	NICE, TA	
Dimitry Pomonarev	NICE, TA	
Marcela Hassova	NICE, TA	
Stephen O'Brien	Committee C Member	
Adam Storrow	NICE, Resource Impact	

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 Palbociclib in combination with an aromatase inhibitor for previously untreated metastatic, hormone receptor-positive, HER2-negative breast cancer [ID915].
2. The Chair informed the Committee of the non-public observers at this meeting
3. Apologies were received from: Dr Graham Ash, Dr Andrew England, Ellen Rule, Dr Mohit Sharma and Mr Stephen Sharp

**Notes from the last meeting**

4. Minutes for the last meeting were agreed.

**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**

5. The Chair welcomed the invited experts: Dr Alistair Ring, Melanie Sturtevant, Angela Stainthorpe and Rumona Dickson to the meeting and they introduced themselves to the Committee.
6. The Chair welcomed company representatives from Pfizer to the meeting.
7. The Chair asked all Committee members to declare any relevant interests
  - 7.1. Dr Jane Adam, Dr Justin Daniels, Mr Adrian Griffin, Dr Rachel Hobson, Professor John McMurray, Dr Minal Bakhai, Mrs Sarah Parry, Ms Pamela Rees, Dr Brian Shine, Mr David Evans, Dr John Watkins, Professor Olivia Wu, Dr Nerys Woolacott, Dr Rita Faria 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 Palbociclib in combination with an aromatase inhibitor for previously untreated metastatic, hormone receptor-positive, HER2-negative breast cancer [ID915]
  - 7.2. Dr Jeremy Braybrooke declared a non-personal specific financial interest as he is coinvestigator on clinical trials with palbociclib and ribociclib in breast cancer. He has no personal pecuniary interest.
    - 3.2.1 It was agreed that this declaration would not prevent Dr Jeremy Braybrooke 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 Palbociclib in combination with an aromatase inhibitor for previously untreated metastatic, hormone receptor-positive, HER2-negative breast cancer [ID915]
9. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.
  - 9.1. Rumona Dickson and Angela Stainthorpe 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 [ID915]

- 9.2. Dr Alistair Ring declared a personal non-specific financial interest as he has received honoraria from Pfizer for providing talks and as a trial chief investigator; has received honoraria from Novartis for a steering committee; and honoraria from Lilly for work on an advisory board.
  - 9.2.1. It was agreed that this declaration would not prevent Dr Alistair Ring from participating in this section of the meeting.
- 9.3. Melanie Sturtevant declared a non-personal non-specific financial interest as Breast Cancer Now has received funding from Pfizer. This is independent of their work on access to drugs.
  - 9.3.1. It was agreed that this declaration would not prevent Melanie Sturtevant from participating in this section of the meeting

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

  

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

**Appraisal of Ribociclib in combination with an aromatase inhibitor for previously untreated advanced or metastatic hormone receptor-positive, HER2-negative breast cancer [ID1026].**

**Part 2a – Closed session**

17. The Chair welcomed the invited experts: Nasuh Buyukkaramikli and Becky Pennington to the meeting and they introduced themselves to the Committee.
18. The Chair welcomed company representatives from Novartis to the meeting.
19. The Chair asked all Committee members to declare any relevant interests Dr Jane Adam, Dr Justin Daniels, Mr Adrian Griffin, Dr Rachel Hobson, Professor John McMurray, Dr Minal Bakhai, Mrs Sarah Parry, Ms Pamela Rees, Dr Brian Shine, Mr David Evans, Dr John Watkins, Professor Olivia Wu, Dr Nerys Woolacott, Dr Rita Faria 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 Ribociclib in combination with an aromatase inhibitor for previously untreated advanced or metastatic hormone receptor-positive, HER2-negative breast cancer to the meeting.
  - 19.1. Dr Jeremy Braybrooke declared a non-personal specific financial interest as he is coinvestigator on clinical trials with palbociclib and ribociclib in breast care. He has no personal pecuniary interest.
    - 12.1.1 It was agreed that this declaration would not prevent Dr Jeremy Braybrooke from participating in this section of the meeting.
- 12.2 Professor John McMurray declared a non-personal non-specific financial interest as his employees Glasgow University has been paid by Novartis for a number of activities including trial communities, advisory boards, research support and lecturing/teaching. He preferred not to participate in the discussion.
  - 12.2.1 It was agreed that this declaration would not prevent Professor John McMurray from participating in this section of the meeting however he remained 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 Ribociclib in combination with an aromatase inhibitor for previously untreated advanced or metastatic hormone receptor-positive, HER2-negative breast cancer
21. The Chair asked all other invited guests (ERG and invited experts, not including observers) to declare their relevant interests.

- 21.1. Nasuh Buyukkaramikli and Becky Pennington both 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 Ribociclib in combination with an aromatase inhibitor for previously untreated advanced or metastatic hormone receptor-positive, HER2-negative breast cancer
22. The Chair introduced the key themes related to this appraisal and the previous discussions.
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 2b – Closed session**

26. Discussion on confidential information continued. This information was supplied by the company.
  - 26.1. The Committee continued to discuss the clinical and cost effectiveness of Ribociclib in combination with an aromatase inhibitor for previously untreated advanced or metastatic hormone receptor-positive, HER2-negative breast cancer
27. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

### **Appraisal of Golimumab for treating non-radiographic axial spondyloarthritis [ID903]**

### **Part 1 – Open session**

28. The Chair welcomed company representatives from Merck Sharpe and Dohme to the meeting.
29. The Chair asked all Committee members to declare any relevant interests
  - 29.1. Dr Jane Adam, Dr Justin Daniels, Dr Rachel Hobson, Dr Minal Bakhai, Dr Ian Bernstein, Mrs Sarah Parry, Ms Pamela Rees, Dr Brian Shine, Mr David Evans, Dr John Watkins, Professor Olivia Wu, Dr Nerys Woolacott and Dr Rita Faria 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 Golimumab for treating non-radiographic axial spondyloarthritis [ID903]

- 29.2. Mr Adrian Griffin declared a personal specific financial interest as golimumab is owned by Johnson and Johnson in the US. It was agreed that the conflict would prohibit him from participating in the meeting and he remained absent.
- 29.3. Dr Paul Robinson declared a personal specific financial interest as golimumab is owned by his employer MSD. It was agreed that the conflict would prohibit him from participating in the meeting and he remained absent.
30. The Chair asked all NICE Staff to declare any relevant interests.
  - 30.1. 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 Golimumab for treating non-radiographic axial spondyloarthritis [ID903]
31. The Chair gave presentations on the clinical effectiveness and cost effectiveness of Golimumab for treating non-radiographic axial spondyloarthritis [ID903]
32. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
33. 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.
34. 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**

35. Discussion on confidential information continued. This information was supplied by the company.
36. The Committee continued to discuss the clinical and cost effectiveness of Golimumab for treating non-radiographic axial spondyloarthritis [ID903]
37. 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**

Thursday 2 November 2017, 10am – 5pm, at Prospero House, 241 Borough High Street, London SE1 1GA.