

## Technology Appraisal Committee Meeting (Committee [A])

**Minutes:** Confirmed

**Date and Time:** 19<sup>th</sup> April 2016, 10

**Venue:**

National Institute for Health and Care Excellence  
10 Spring Gardens  
SW1A 2BU

**Present:**

1. Chair Dr Jane Adam
2. Professor Iain Squire
3. Dr Brian Shine
4. Dr Jeremy Braybrooke
5. Dr Justin Daniels
6. Mr Stephen Sharp
7. Dr Graham Ash
8. Dr Gerardine Bryant
9. Dr Andrew England
10. Dr Rachel Hobson
11. Mrs Sarah Parry
12. Miss Pamela Rees
13. Dr Paul Robinson
14. Ms Ellen Rule
15. Mr David Thomson
16. Dr John Watkins
17. Professor Olivia Wu
18. Dr Nerys Woolacott

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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
Marcia Miller	Technology Administrator, National Institute for Health and Care Excellence	Present for all notes
Eleanor Donegan	Technical Advisor, National Institute for Health and Care Excellence	Present for notes 1 to 16
Richard Diaz	Technical Analyst, National Institute for Health and Clinical Excellence	Present for notes 1 to 16
Joanna Richardson	Technical Advisor, National Institute for Health and Care Excellence	Present for Notes 17 to 28
Carl Prescott	Technical Analyst, National Institute for Health and Clinical Excellence	Present for Notes 17 to 28
Eleanor Donegan	Technical Advisor, National Institute for Health and Care Excellence	<b>Present for notes</b>
Irina Voicechovskaja	Technical Analyst, National Institute for Health and Clinical Excellence	<b><i>Present for notes</i></b>
<b>Evidence Review Group</b>		
Andrea Berardi	Health Economics, BMJ -TAG	Present for Notes 1 to 14
Steve Edwards	Head of Economic, BMJ TAG	Present for Notes 1 to 14
Charlotta Karner	Health Economics, BMJ -TAG	Present for Notes 1 to 14
<b>Evidence Review Group</b>		Present for Notes
Hazel Squires	Health Economics, ScHARR	Present for Notes 17 to 25
John Steven	Health Economics, ScHARR	Present for Notes 17 to 25
Abdullah Pandor	Health Economics, ScHARR	Present for Notes 17 to 25
<b>Observers</b>		
<b>Hamish Lunagaria</b>	NICE, CHTE TA	
<b>Sana Khan</b>	NICE CHTE TA	
<b>Oliver Michelson</b>	NICE, Comms	
<b>Praveen Patel</b>	ScHARR	
<b>Vassilia Verdiel</b>	NICE, IP	

## 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 **Nivolumab in combination with ipilimumab for advanced, unresectable melanoma**.
2. The Chair informed the Committee of the non-public observers at this meeting: Hamish Lunagaria, Sana Khan, Oliver Michelson, Vassilia Verdiel and Praveen Patel
3. Apologies were received from: Mr Adrian Griffin, Dr Anne McCune, Professor John McMurray and Dr Mohit Misra

### Notes from the last meeting

4. The minutes for the last meeting were agreed.

### Appraisal of Nivolumab in combination with ipilimumab for advanced, unresectable melanoma

#### Part 1 – Open session

5. The Chair welcomed the invited experts **and ERG representatives** : Andrea Beardi, Steve Edwards, Dr Sarah Danson, Dr James Larkin and Charlotta Karner to the meeting and they introduced themselves to the Committee.
6. The Chair welcomed company representatives from Bristol Myers-Squibb 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, Dr Justin Daniels, Mr Stephen Sharp, Dr Graham Ash, Dr Gerardine Bryant, Dr Andrew England, Dr Rachel Hobson, Mrs Sarah Parry Miss Pamela Rees, Ms Ellen Rule, Mr David Thomson, Dr John Watkins 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 **Nivolumab in combination with ipilimumab for advanced, unresectable melanoma.**

- 7.2. Dr Jeremy Braybrooke declared a non-personal specific financial interest as he has been an investigator on breast cancer trials sponsored by Roche, that have recruited patients.
  - 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 Paul Robinson declared a personal specific pecuniary interest as he has a direct conflict with Roche. Dr Paul Robinson 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 **Nivolumab in combination with ipilimumab for advanced, unresectable melanoma.**
  - 8.2. 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 **Nivolumab in combination with ipilimumab for advanced, unresectable melanoma.**
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 **Nivolumab in combination with ipilimumab for advanced, unresectable melanoma.**
  - 9.2. Dr Sarah Danson declared a personal non-specific financial interest as she has received expenses for travel payment for attending meeting for BMS. Dr Sarah Danson also declared a non-personal specific as she has been PI on trials with these agents. She submitted a trial proposal to HTA which involves the use of nivolumab.
    - 9.2.1. It was agreed that this declaration would not prevent Dr Sarah Danson from participating in this section of the meeting
  - 9.3. Dr James Larkin declared a personal non-specific as he acted as an expert adviser invited by BMS at the Oral Explanation in front of the

CHMP on 26th January 2016 for the discussion of combination of ipilimumab and nivolumab for the treatment of advanced melanoma.

9.3.1. It was agreed that this declaration would not prevent Dr James Larkin from participating in this section of the meeting

9.4. Mr Mel Jones declared a non personal, non specific financial interest declaration as his wife holds 2k worth of shares in BMS.

9.4.1. It was agreed that this declaration would not prevent Mr Mel Jones from participating in this section of the meeting

10. The Chair introduced the lead team, Dr Jeremy Braybrooke, Dr Brian Shine and Pamela Rees who gave presentations on the clinical effectiveness and cost effectiveness of **Nivolumab in combination with ipilimumab for advanced, unresectable melanoma.**
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 Nivolumab in combination with ipilimumab for advanced, unresectable melanoma.**
16. The Committee instructed the technical team to prepare the **Final Appraisal Determination (FAD)** in line with their decisions.

## Appraisal of Pertuzumab for the neoadjuvant treatment of HER2-positive breast cancer [ID767]

### Part 1 – Open session

17. The Chair welcomed the invited experts **and ERG representatives**: Dr Andrew Wardley, Dr Stuart McIntosh, Miss Jayne Hawkins, Hazel Squires, John Stevens and Abdullah Pandor to the meeting and they introduced themselves to the Committee.
18. The Chair welcomed company representatives from Roche **to the meeting**.
19. The Chair asked all Committee members to declare any relevant interests
  - 19.1. Dr Jane Adam, Professor Iain Squire, Dr Brian Shine, Dr Justin Daniels, Mr Stephen Sharp, Dr Graham Ash, Dr Gerardine Bryant, Dr Andrew England, Dr Rachel Hobson, Mrs Sarah Parry, Miss Pamela Rees, Dr Paul Robinson, Ms Ellen Rule, Mr David Thomson, Dr John Watkins, 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 **Pertuzumab for the neoadjuvant treatment of HER2-positive breast cancer [ID767]**
  - 19.2. Dr Jeremy Braybrooke declared a non-personal specific financial interest as he has been an investigator on breast cancer trials sponsored by Roche, that have recruited patients.
  - 19.3. 9.2.1 It was agreed that this declaration would not prevent Dr Jeremy Braybrooke from participating in this section of 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 **Pertuzumab for the neoadjuvant treatment of HER2-positive breast cancer**.
21. The Chair asked all other invited guests (ERG and invited experts, not including observers) to declare their relevant interests.
  - 21.1. Dr Stuart McIntosh, Miss Jayne Hawkins, Hazel Squires, John Stevens and Abdullah Pandor 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 **Pertuzumab for the neoadjuvant treatment of HER2-positive breast cancer**.
  - 21.2. Dr Andrew Wardley declared a personal non-specific financial interest as he had sat on advisory boards for Roche.

21.2.1. It was agreed that this declaration would not prevent Dr Andrew Wardley from participating in this section of the meeting

22. The Chair introduced the lead team, Dr Justin Daniels, Mr Stephen Sharp and **Mr David Thomson** who gave presentations on the clinical effectiveness and cost effectiveness of **Pertuzumab for the neoadjuvant treatment of HER2-positive breast cancer**.
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 **Pertuzumab for the neoadjuvant treatment of HER2-positive breast cancer**.
28. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD)

## Appraisal of Talimogene laherparepvec for treating metastatic melanoma [ID508]

### Part 1 – Open session

29. The Chair welcomed the invited experts: Dr Christian Ottensmeier and Dr Kevin Harrington to the meeting and they introduced themselves to the Committee.
30. The Chair welcomed company representatives from **Talimogene laherparepvec for treating metastatic melanoma** to the meeting.
31. The Chair asked all Committee members to declare any relevant interests
  - 31.1. Dr Jane Adam, Dr Brian Shine, Dr Justin Daniels, Mr Stephen Sharp, Dr Graham Ash, Dr Gerardine Bryant, Dr Andrew England, Dr Rachel Hobson, Mrs Sarah Parry Miss Pamela Rees, Dr Paul Robinson, Ms Ellen Rule, Mr David Thomson, Dr John Watkins 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 Talimogene laherparepvec for treating metastatic melanoma
  - 31.2. Professor Iain Squire declared a non-personal interest financial interest as he has received honoraria from Novartis for participation in advisory Boards and for participation in educational events. None of these are in the same disease area as this technology appraisal, but relate to heart failure.
    - 9.2.1 It was agreed that this declaration would not prevent Professor Iain Squire from participating in this section of the meeting.
  - 31.3. Dr Paul Robinson declared a personal specific interest as his employer MSD is the company of a comparator technology. Dr Paul Robinson 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 **Talimogene laherparepvec for treating metastatic melanoma**.
33. The Chair asked all other invited guests to declare their relevant interests
  - 33.1. Professor Kevin Harrington declared a personal non-pecuniary interest as he is involved in clinical trials with T-Vec.
    - 33.1.1. It was agreed that this declaration would not prevent Professor Kevin Harrington from participating in this section of the meeting



- 33.2. Professor Christian Ottensmier declared a personal specific-pecuniary financial interest as has received grant funding for a clinical trial jointly by Amgen and CR UK for a different Amgen compound in a phase II clinical trial in head and neck cancer.
- 33.2.1. It was agreed that this declaration would not prevent Professor Christian Ottensmier from participating in this section of the meeting
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 **Talimogene laherparepvec for treating metastatic melanoma**
40. The Committee agreed to defer a decision on the content of the guidance section of the Appraisal Consultation Document (ACD) or Final Appraisal Determination (FAD)] until additional work by the ERG has been undertaken.

## **Date, time and venue of the next meeting**

41. Tuesday 17<sup>th</sup> May 2016 - 10am at the National Institute for Health and Care Excellence,  
10 Spring Gardens, London SW1A 2BU.