

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

**Minutes:** [Confirmed]

**Date and Time:** 17<sup>th</sup> May 2016, 10am

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

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|-----------------|----------------------------|-----------------------|
| <b>Present:</b> | 1. Chair Jane Adam         | Present for all notes |
|                 | 2. Professor Iain Squire   | Present for all notes |
|                 | 3. Dr Jeremy Braybrook     | Present for all notes |
|                 | 4. Dr Justine Daniels      | Present for all notes |
|                 | 5. Dr Andrew England       | Present for all notes |
|                 | 6. Mr Adrian Griffin       | Present for all notes |
|                 | 7. Dr Rachel Hobson        | Present for all notes |
|                 | 8. Dr Anne McCune          | Present for all notes |
|                 | 9. Professor John McMurray | Present for all notes |
|                 | 10. Miss Pamela Rees       | Present for all notes |
|                 | 11. Dr Paul Robinson       | Present for all notes |
|                 | 12. Mr Stephen Sharp       | Present for all notes |
|                 | 13. Dr Brian Shine         | Present for all notes |
|                 | 14. Mr David Thomson       | Present for all notes |
|                 | 15. Dr John Watkins        | Present for all notes |
|                 | 16. Professor Olivia Wu    | Present for all notes |
|                 | 17. Dr Nerys Woolacott     | Present for all notes |

### In attendance:

|                 |  |                       |
|-----------------|--|-----------------------|
| Meindert Boysen | Programme Director,<br>National Institute for<br>Health and Care<br>Excellence | Present for all notes |
| Janet Robertson | Associate Director,<br>National Institute for<br>Health and Care<br>Excellence | Present for all notes |
| Liv Gualda      | Project Manager,<br>National Institute for<br>Health and Care<br>Excellence    | Present for all notes |
| Marcia Miller   | Technology Appraisal<br>Administrator, National                                | Present for all notes |

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| Mary Hughes | Technical Analyst,<br>National Institute for<br>Health and Care<br>Excellence | Present for notes all notes |
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| Joanna Richardson | Technical Adviser,<br>National Institute for<br>Health and Clinical<br>Excellence | Present for notes all notes |
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**Evidence Review  
Group**

|                   |                              |                       |
|-------------------|------------------------------|-----------------------|
| Keith Cooper      | Senior Research Fellow       | Present for notes 1-9 |
| Jonathan Shepherd | Principle Research<br>Fellow | Present for notes 1-9 |

|             |  |                       |
|-------------|--|-----------------------|
| Joanne Lord |  | Present for notes 1-9 |
|-------------|--|-----------------------|

**Clinical Experts**

|                 |   |                       |
|-----------------|---|-----------------------|
| Dr James Larkin | Consultant Medical<br>Oncologist, nominated by<br>RCP | Present for notes 1-9 |
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**Patient Expert**

|              |  |                       |
|--------------|--|-----------------------|
| Mr Mel Jones | Patient expert nominated<br>by Melanoma UK | Present for notes 1-9 |
|--------------|--|-----------------------|

**Non-public observers:**

|              |             |                             |
|--------------|-------------|-----------------------------|
| Jade Fortune | <b>NICE</b> | Present for notes all notes |
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|                  |                        |                             |
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| Adam Sorrow      | NICE,                  | Present for notes all notes |
| Chloe Kastoryano | NICE, PPIP             | Present for notes all notes |
| Joshua South     | NICE, Corporate Office | Present for notes 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 cobimetinib in combination with vemurafenib for treating advanced (unresectable or metastatic) BRAF V600 mutation-positive melanoma [ID815]
2. The Chair informed the Committee of the non-public observers at this meeting: Jade Fortune, Chloe Kastoryano, Adam Sorrow and Joshua South.
3. Apologies were received from Dr Graham Ash, Dr Mohit Misra, Mrs Sarah Parry and Ms Ellen Rule.

**Notes from the last meeting**

4. The minutes of the last meeting were agreed.
5. **Appraisal of** cobimetinib in combination with vemurafenib for treating advanced (unresectable or metastatic) BRAF V600 mutation-positive melanoma [ID815]

## Part 1 – Open session

1. The Chair welcomed the invited experts: Keith Cooper, Dr James Larkin, Mr Mel Jones. Dr Jonathan Shepherd and Joanne Lord to the meeting and they introduced themselves to the Committee.
2. The Chair welcomed company representatives from Roche to the meeting.
3. The Chair asked all Committee members to declare any relevant interests
  - 3.1. Chair Jane Adam, Dr Justin Daniels, Dr Andrew England, Mr Adrian Griffin, Dr Rachel Hobson, Dr Anne McCune, Professor John McMurray, Miss Pamela Rees, Dr Paul Robinson, Mr Stephen Sharp, Dr Brian Shine, Mr David Thomson, Dr John Watkins, Professor Olivia Wu, 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 cobimetinib in combination with vemurafenib for treating advanced (unresectable or metastatic) BRAF V600 mutation-positive melanoma.
  - 3.2. Professor Iain Squire declared a non-personal non-specific financial interest as he has accepted honoraria from Novartis for participation in advisory boards and educational events. These events were all in the area of heart failure, unrelated to the appraisal.
    - 9.2.1 It was agreed that this declaration would not prevent Professor Iain Squire from participating in this section of the meeting.
  - 3.3. Dr Jeremy Braybrooke declared a non-personal non-specific financial interest as he has been involved in recruitment of patients into clinical trials in breast cancer relating to Roche
    - 9.3.1 It was agreed that this declaration would not prevent Dr Jeremy Braybrooke from participating in this section of the meeting.
  - 3.4. Dr Paul Robinson declared that his employer Merck Sharp and Dohme have a product for the same disease (metastatic melanoma), but not when a BRAF treatment strategy has been adopted.
    - 9.3.1 It was agreed that this declaration would not prevent Dr Paul Robinson from participating in this section of the meeting.
4. The Chair asked all NICE Staff to declare any relevant interests.
  - 4.1. 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 cobimetinib in

combination with vemurafenib for treating advanced (unresectable or metastatic) BRAF V600 mutation-positive melanoma

5. The Chair asked all other invited guests (ERG and invited experts, not including observers) to declare their relevant interests.
  - 5.1. Keith Cooper, Dr Jonathan Shepherd and Joanne Lord 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 cobimetinib in combination with vemurafenib for treating advanced (unresectable or metastatic) BRAF V600 mutation-positive melanoma
  - 5.2. Dr James Larkin declared a personal specific financial interest 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.'
  - 5.3.
    - 5.3.1. It was agreed that this declaration would not prevent Dr James Larkin from participating in this section of the meeting
  - 5.4. Mr Mel Jones declared a non-personal non-specific financial interest as he participated in a twitter awareness campaign with Roche for melanoma.
    - 5.4.1. It was agreed that this declaration would not prevent Mr Mel Jones from participating in this section of the meeting.
6. The Chair introduced the lead team, Dr Rachel Hobson, Mr Adrian Griffin and Mr David Thomson who gave presentations on the clinical effectiveness and cost effectiveness of cobimetinib in combination with vemurafenib for treating advanced (unresectable or metastatic) BRAF V600 mutation-positive melanoma
7. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
8. 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.
9. 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**

10. Discussion on confidential information continued. This information was supplied by the company.

11. The Committee continued to discuss the clinical and cost effectiveness of cobimetinib in combination with vemurafenib for treating advanced (unresectable or metastatic) BRAF V600 mutation-positive melanoma
12. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.
13. ***Tuesday 21<sup>st</sup> June 2016 at 10am*** Prospero House, 241 Borough High Street, London SE1 1GA