Technology Appraisal Committee Meeting (Committee B)

Minutes: Confirmed

Date and Time: Wednesday 8 June 2016, 10am to 5pm

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

Present:

1. Dr Amanda Adler (Chair) Present for all notes
2. Dr Sanjeev Patel (Vice-Chair) Present for all notes
3. Dr Ray Armstrong Present for all notes
4. Dr Jeffrey Aronson Present for all notes
5. Professor John Cairns Present for all notes
6. Mr Mark Chapman Present for all notes
7. Dr Mark Glover Present for all notes
8. Dr Neil Iosson Present for all notes
9. Ms Anne Joshua Present for all notes
10. Dr Sanjay Kinra Present for all notes
11. Mr Christopher O’Regan Present for all notes
12. Professor Stephen Palmer Present for all notes
13. Dr Danielle Preedy Present for all notes
14. Ms Marta Soares Present for notes 1 to 16
15. Professor Ken Stein Present for all notes
16. Mr Nigel Westwood Present for all notes

In attendance:

Meindert Boysen Programme Director, National Institute for Health and Care Excellence Present for notes 1 to 16

Dr Melinda Goodall Associate Director, National Institute for Health and Care Excellence Present for all notes

Jeremy Powell Project Manager, National Institute for Health and Care Excellence Present for all notes

Naomi Robertson Administrator, National Institute for Health and Care Excellence Present for all notes

Ahmed Elsada Technical Analyst, Present for notes 1 to 16
<table>
<thead>
<tr>
<th>Name</th>
<th>Position and Affiliation</th>
<th>Present for notes</th>
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<tr>
<td>Raisa Sidhu</td>
<td>Technical Adviser, National Institute for Health and Clinical Excellence</td>
<td>1 to 16</td>
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<tr>
<td>Anna Brett</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>17 to 29</td>
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<tr>
<td>Dr Rosie Lovett</td>
<td>Technical Adviser, National Institute for Health and Clinical Excellence</td>
<td>17 to 29</td>
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<tr>
<td>Dr Bram Ramaekers</td>
<td>Health Economist, Kleijnen Systematic Reviews</td>
<td>1 to 14</td>
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<tr>
<td>Mr Robert Wolff</td>
<td>Systematic Reviewer, Kleijnen Systematic Reviews</td>
<td>1 to 14</td>
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<tr>
<td>Dr Richard Adams</td>
<td>Consultant Oncologist, Velindre NHS Trust, clinical expert, nominated by Servier</td>
<td>1 to 14</td>
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<tr>
<td>Dr Mark Saunders</td>
<td>Consultant Clinical Oncologist, the Christie, clinical expert, nominated by Servier</td>
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<tr>
<td>Ms Helena Hanratty</td>
<td>Nurse Advisor, Beating Bowel Cancer, patient expert, nominated by Beating Bower Cancer</td>
<td>1 to 14</td>
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<tr>
<td>Ms Andrea Berardi</td>
<td>HE Manager, BMJ Technology Assessment Group</td>
<td>17 to 27</td>
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<td>Dr Steve Edwards</td>
<td>Head of Clinical and Economic Evidence, BMJ Technology Assessment Group</td>
<td>17 to 27</td>
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<tr>
<td>Dr Charlotta Karner</td>
<td>HTA Analysis Manager, BMJ Technology Assessment Group</td>
<td>17 to 27</td>
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Dr James Larkin  Consultant Medical Oncologist, the Royal Marsden Hospital, clinical expert, nominated by Bristol Myers Squibb Present for notes 17 to 25

Dr Paul Nathan  Consultant Medical Oncologist, Mount Vernon Cancer Centre, clinical expert, nominated by NCRI Bladder & Renal Cancer CSG-RCP-ACP-RCR Present for notes 17 to 25

Mr Jon Birchall  Patient expert, nominated by the Kidney Cancer Support Network Present for notes 17 to 25

Ms Alison Fielding  Patient expert, nominated by the Kidney Cancer Support Network Present for notes 17 to 25

**Non-public observers:**

Helen Barnett  Medical Editor, NICE Present for all notes

Liv Gualda  Project Manager, NICE Present for all notes

Chloe Kastoryano  Public Involvement Adviser, Patient Involvement Programme, NICE Present for all notes

Edgar Masanga  Business Analyst - Resource Impact Assessment, NICE Present for all notes

Marcia Miller  Administrator, NICE Present for all notes

Raisa Sidhu  Technical Advisor, NICE Present for notes 17 to 29

**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 trifluridine–tipiracil hydrochloride for previously treated metastatic colorectal cancer [ID876] and nivolumab for previously treated advanced renal cell carcinoma [ID853].
2. The Chair informed the Committee of the non-public observers at this meeting: Helen Barnett, Liv Gualda, Chloe Kastoryano, Edgar Masanga, Marcia Miller, and Raisa Sidhu

3. Apologies were received from Dr Rebecca Kearney, Dr Miriam McCarthy, Professor Ruairidh Milne, Professor John Pounsford, Mr Alun Roebuck, Dr Nigel De-Kare Silver, and Dr Nicky Welton

Any other Business

4. The Committee were given an update on the progress of other appraisals.

Notes from the last meeting

5. The minutes of the meetings held on 6 April and 5 May were approved.

Appraisal of trifluridine–tipiracil hydrochloride for previously treated metastatic colorectal cancer [ID876]

Part 1 – Open session

6. The Chair welcomed the invited experts: Dr Richard Adams, Ms Helena Hanratty, Dr Bram Ramaekers, Dr Mark Saunders, and Mr Robert Wolff to the meeting and they introduced themselves to the Committee.

7. The Chair welcomed company representatives from Servier to the meeting.

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

8.1. Dr Amanda Adler, Dr Ray Armstrong, Dr Jeff Aronson, Professor John Cairns, Mr Mark Chapman, Dr Mark Glover, Dr Neil losson, Ms Anne Joshua, Dr Sanjay Kinra, Mr Christopher O'Regan, Professor Stephen Palmer, Dr Sanjeev Patel, Dr Danielle Preedy, Ms Marta Soares, Professor Ken Stein, and Mr Nigel Westwood 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 trifluridine–tipiracil hydrochloride for previously treated metastatic colorectal cancer [ID876].

9. The Chair asked all NICE Staff to declare any 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 trifluridine–tipiracil hydrochloride for previously treated metastatic colorectal cancer [ID876].

10. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.

10.1. Ms Helena Hanratty, Dr Bram Ramaekers, and Mr 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 trifluridine–tipiracil hydrochloride for previously treated metastatic colorectal cancer [ID876].

10.2. Dr Richard Adams declared a personal specific financial interest as he has received advisory board fees from Servier and travel fees and an educational grant from other companies. 10.2.1. It was agreed that this declaration would not prevent Dr Richard Adams from participating in this section of the meeting

10.3. Dr Mark Saunders declared a personal specific financial interest as he was a paid advisor on an advisory board for Servier and an advisor on their submission for NICE. Dr Mark Saunders was also the chief investigator on a new first line trial with trifluridine and tipiracil hydrochloride. Additionally, Dr Mark Saunders received an educational grant from Servier. Finally, Dr Mark Saunders is the chair of the medical advisory board of Beating Bowel Cancer. 10.3.1. It was agreed that this declaration would not prevent Dr Mark Saunders from participating in this section of the meeting

11. The Chair introduced the lead team, Mr Christopher O’Regan, Dr Sanjeev Patel, Dr Danielle Preedy who gave presentations on the clinical effectiveness and cost effectiveness of trifluridine–tipiracil hydrochloride for previously treated metastatic colorectal cancer [ID876].

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, Evidence Review Group and company representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

Part 2 – Closed session

15. The Committee continued to discuss the clinical and cost effectiveness of trifluridine–tipiracil hydrochloride for previously treated metastatic colorectal cancer [ID876].

15.1. The committee decision was based on consensus.

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

Appraisal of nivolumab for previously treated advanced renal cell carcinoma [ID853]

Part 1 – Open session
17. The Chair welcomed the invited experts: Ms Andrea Berardi, Mr Jon Birchall, Dr Steve Edwards, Ms Alison Fielding, Dr Charlotta Karner, Dr James Larkin, and Dr Paul Nathan to the meeting and they introduced themselves to the Committee.

18. The Chair welcomed company representatives from Bristol-Myers Squibb to the meeting.

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

19.1. Dr Amanda Adler, Dr Ray Armstrong, Dr Jeff Aronson, Professor John Cairns, Mr Mark Chapman, Dr Mark Glover, Dr Neil Iosson, Ms Anne Joshua, Dr Sanjay Kinra, Mr Christopher O'Regan, Professor Stephen Palmer, Dr Sanjeev Patel, Dr Danielle Preedy, Professor Ken Stein, and Mr Nigel Westwood 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 for previously treated advanced renal cell carcinoma [ID853].

19.2. Ms Marta Soares was absent because she had previously declared a personal specific financial interest as she had participated in an advisory board for Bristol-Myers Squibb for this indication of nivolumab.

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 nivolumab for previously treated advanced renal cell carcinoma [ID853].

21. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.

21.1. Ms Andrea Berardi, Mr Jon Birchall, Dr Steve Edwards, Ms Alison Fielding and Dr Charlotta Karner 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 for previously treated advanced renal cell carcinoma [ID853].

21.2. Dr James Larkin declared a non-personal non-financial interest as he was a co-author on a trial of nivolumab and worked with Bristol-Myers Squibb on other trials.  
21.2.1. It was agreed that this declaration would not prevent Dr James Larkin from participating in this section of the meeting.

21.3. Dr Paul Nathan declared a personal specific financial interest as he had been an advisory board member for companies including Bristol-Myers Squibb.  
21.3.1. It was agreed that this declaration would not prevent Dr Paul Nathan from participating in this section of the meeting.
22. The Chair introduced the lead team, Ms Anne Joshua, Professor Stephen Palmer, and Mr Nigel Westwood who gave presentations on the clinical effectiveness and cost effectiveness of nivolumab for previously treated advanced renal cell carcinoma [ID853].

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 Evidence Review Group representatives left the meeting.

28. The Committee continued to discuss the clinical and cost effectiveness of nivolumab for previously treated advanced renal cell carcinoma [ID853].

   28.1. The committee decision was based on consensus.

29. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.

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

Wednesday 6 July 2016, 10am at Prospero House, 241 Borough High Street, London, SE1 1GA