

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

	National Institute for Health and Care Excellence	
Raisa Sidhu	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 1 to 16
Anna Brett	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 17 to 29
Dr Rosie Lovett	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 17 to 29
Dr Bram Ramaekers	Health Economist, Kleijnen Systematic Reviews	Present for notes 1 to 14
Mr Robert Wolff	Systematic Reviewer, Kleijnen Systematic Reviews	Present for notes 1 to 14
Dr Richard Adams	Consultant Oncologist, Velindre NHS Trust, clinical expert, nominated by Servier	Present for notes 1 to 14
Dr Mark Saunders	Consultant Clinical Oncologist, the Christie, clinical expert, nominated by Servier	Present for notes 1 to 14
Ms Helena Hanratty	Nurse Advisor, Beating Bowel Cancer, patient expert, nominated by Beating Bower Cancer	Present for notes 1 to 14
Ms Andrea Berardi	HE Manager, BMJ Technology Assessment Group	Present for notes 17 to 27
Dr Steve Edwards	Head of Clinical and Economic Evidence, BMJ Technology Assessment Group	Present for notes 17 to 27
Dr Charlotta Karner	HTA Analysis Manager, BMJ Technology Assessment Group	Present for notes 17 to 27

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 Poundsford, 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 Iosson, 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 Fieldin 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