

## Technology Appraisal Committee Meeting (CDF Committee)

**Minutes:** **Unconfirmed**

**Date and Time:** **Tuesday 26 July, 10.00am to 4.30pm**

**Venue:** National Institute for Health and Care Excellence  
Level 1A, City Tower  
Piccadilly Plaza  
Manchester  
M1 4BT

<b>Present:</b>	1. Chair Dr Amanda Adler 2. Dr Anna O'Neill 3. Dr Brian Shine 4. Christopher O'Regan 5. Professor David Bowen 6. David Chandler 7. Professor Eugene Milne 8. Gail Coster 9. Ian Davidson 10. Jeff Aronson 11. Judith Wardle 12. Mark Chapman 13. Professor Matt Stevenson 14. Matthew Bradley 15. Professor Rachel Elliott 16. Professor Stephen O'Brien 17. Susan Griffin 18. Dr Olivia Wu	Present for all notes Present for notes 1 to 26 Present for notes 1 to 26 Present for notes 1 to 35
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### In attendance:

Meindert Boysen	Programme Director, National Institute for Health and Care Excellence	Present for all notes
Professor Carole Longson	Centre Director, National Institute for Health and Care Excellence	Present for all notes
Helen Knight	Associate Director Manager, National Institute for Health and Care Excellence	Present for notes 1 to 14
Dr Frances Sutcliffe	Associate Director, National Institute for Health and Care Excellence	Present for notes 15 to 26

Amaka Umeweni	Technical Advisor, National Institute for Health and Care Excellence	Present for notes 1 to 14
Jenna Dilkes	Project Manager, National Institute for Health and Care Excellence	Present for all notes
Carl Jackson	Administrator, National Institute for Health and Clinical Excellence	Present for all notes
Graham Scotland	ERG Representative	Present for notes 1 to 14
Indigo Bermejo	ERG Representative	Present for notes 15 to 26
Sabine Grimm	ERG Representative	Present for notes 15 to 26
Adrian Bagust	ERG Representative	Present for notes 27 to 39
Peter Clark	CDF Clinical Lead	Present for all notes
Dr Amit Bahl	Clinical Expert	Present for notes 1 to 14
Hugh Gunn	Patient Expert	Present for notes 1 to 14
Jennifer Wood	Clinical Expert	Present for notes 15 to 26
Andrew Langford	Patient Expert	Present for notes 15 to 26
Tamara Sandoul	Patient Expert	Present for notes 27 to 39

**Non-public observers:**

Henry Edwards	NICE Observer	Present for notes 15 to 39
Helen Barnett	NICE Observer	Present for all notes
Laura Norburn	NICE Observer	Present for all notes
Linda Landells	NICE Observer	Present for 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 Radium-223 dichloride for treating metastatic hormone relapsed prostate cancer with bone metastases (review of TA376),

Sorafenib for advanced hepatocellular carcinoma (review of TA189) and Everolimus in combination with exemestane for treating advanced HER2-negative hormone-receptor-positive breast cancer after endocrine therapy (review of TA295).

## **Any other Business**

2. None

## **Appraisal of Radium-223 dichloride for treating metastatic hormone relapsed prostate cancer with bone metastases (review of TA376)**

### **Part 1 – Open session**

3. The Chair welcomed the invited experts: Peter Clark, Dr Amit Bahl, Graham Scotland and Hugh Gunn to the meeting and they introduced themselves to the Committee.
4. The Chair welcomed company representatives from Bayer PLC to the meeting.
5. The Chair asked all Committee members to declare any relevant interests
  - 5.1. Dr Amanda Adler, Jeff Aronson, Professor David Bowen, Matthew Bradley, David Chandler, Mark Chapman, Gail Coster, Ian Davidson, Professor Rachel Elliott, Susan Griffin, Professor Eugene Milne, Anna O'Neill, Christopher O'Regan, Professor Stephen O'Brien, Professor Matt Stevenson, Judith Wardle and Dr Olivia Wu 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 Radium-223 dichloride for treating metastatic hormone relapsed prostate cancer with bone metastases (review of TA376)
6. The Chair asked all NICE Staff to declare any relevant interests.
  - 6.1. 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 Radium-223 dichloride for treating metastatic hormone relapsed prostate cancer with bone metastases (review of TA376)
7. The Chair asked all other invited guests (ERG and invited experts, not including observers) to declare their relevant interests.
  - 7.1. Peter Clark and Graham Scotland declared that he 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 Radium-223 dichloride for treating metastatic hormone relapsed prostate cancer with bone metastases (review of TA376).

- 7.2. Hugh Gunn declared a non-personal non-specific financial interest as his organisation Tackle Prostate Cancer received money from Bayer for educational survey.
  - 7.2.1. It was agreed that this declaration would not prevent Hugh Gunn from participating in this section of the meeting
- 7.3. Dr Amit Bahl declared a personal non-specific financial interest as he received honorarium and meeting sponsorships from Bayer.
  - 7.3.1. It was agreed that this declaration would not prevent Dr Amit Bahl from participating in this section of the meeting

8. The Chair gave presentations on the clinical effectiveness and cost effectiveness of Radium-223 dichloride for treating metastatic hormone relapsed prostate cancer with bone metastases (review of TA376).
9. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
10. 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.
11. 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**

12. Discussion on confidential information continued. This information was supplied by the company.
13. The Committee continued to discuss the clinical and cost effectiveness of Radium-223 dichloride for treating metastatic hormone relapsed prostate cancer with bone metastases (review of TA376).
  - 13.1. The committee decision was based on consensus.
14. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

## **Appraisal of Sorafenib for advanced hepatocellular carcinoma (review of TA189)**

### **Part 1 – Open session**

15. The Chair welcomed the invited experts: Peter Clark, Andrew Langford and Jennifer Wood via T/C to the meeting and they introduced themselves to the Committee.
16. The Chair welcomed company representatives from Bayer PLC to the meeting.
17. The Chair asked all Committee members to declare any relevant interests

- 17.1. Dr Amanda Adler, Jeff Aronson, Professor David Bowen, Matthew Bradley, David Chandler, Mark Chapman, Gail Coster, Ian Davidson, Professor Rachel Elliott, Susan Griffin, Professor Eugene Milne, Anna O'Neill, Christopher O'Regan, Professor Matt Stevenson, Judith Wardle and Dr Olivia Wu 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 Sorafenib for advanced hepatocellular carcinoma (review of TA189)
- 17.2. Professor Stephen O'Brien declared a non-personal non-specific financial interest as Pfizer had supported research at University.  
9.2.1 It was agreed that this declaration would not prevent Professor Stephen O'Brien from participating in this section of the meeting.
18. The Chair asked all NICE Staff to declare any relevant interests.
  - 18.1. 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 Sorafenib for advanced hepatocellular carcinoma (review of TA189)
19. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.
  - 19.1. 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 Sorafenib for advanced hepatocellular carcinoma (review of TA189)
20. The Chair gave presentations on the clinical effectiveness and cost effectiveness of Sorafenib for advanced hepatocellular carcinoma (review of TA189)
21. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
22. 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.
23. 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**

24. Discussion on confidential information continued. This information was supplied by the company.
25. The Committee continued to discuss the clinical and cost effectiveness of Sorafenib for advanced hepatocellular carcinoma (review of TA189)
  - 25.1. The committee decision was based on consensus.
26. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.

**Appraisal of Everolimus in combination with exemestane for treating advanced HER2-negative hormone-receptor-positive breast cancer after endocrine therapy (review of TA295)**

**Part 1 – Open session**

27. The Chair welcomed the invited experts: Peter Clark and Tamara Sandoul to the meeting and they introduced themselves to the Committee.
28. The Chair welcomed company representatives from Novartis to the meeting.
29. The Chair asked all Committee members to declare any relevant interests
  - 29.1. Dr Amanda Adler, Jeff Aronson, Professor David Bowen, David Chandler, Mark Chapman, Gail Coster, Ian Davidson, Professor Rachel Elliott, Susan Griffin, Professor Eugene Milne, Anna O'Neill, Christopher O'Regan, Professor Matt Stevenson, Judith Wardle and Dr Olivia Wu 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 Everolimus in combination with exemestane for treating advanced HER2-negative hormone-receptor-positive breast cancer after endocrine therapy (review of TA295)
  - 29.2. Matthew Bradley declared a personal non-specific financial interest as he holds shares in AstraZeneca.
    - 9.2.1 It was agreed that this declaration would not prevent Matthew Bradley from participating in this section of the meeting.
  - 29.3. Susan Griffin declared a personal specific financial interest as she took part in an advisory board and was personally reimbursed by Novartis.
    - 9.3.1 It was agreed that this declaration would prevent Susan Griffin from participating in this section of the meeting.
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 Everolimus in combination with exemestane for treating advanced HER2-negative

hormone-receptor-positive breast cancer after endocrine therapy (review of TA295)

31. The Chair asked all other invited guests (ERG and invited experts, not including observers) to declare their relevant interests.
  - 31.1. 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 Everolimus in combination with exemestane for treating advanced HER2-negative hormone-receptor-positive breast cancer after endocrine therapy (review of TA295)
32. The Chair gave presentations on the clinical effectiveness and cost effectiveness of Everolimus in combination with exemestane for treating advanced HER2-negative hormone-receptor-positive breast cancer after endocrine therapy (review of TA295)
33. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
34. 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.
35. 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**

36. Discussion on confidential information continued. This information was supplied by the company.
37. The Committee continued to discuss the clinical and cost effectiveness of Everolimus in combination with exemestane for treating advanced HER2-negative hormone-receptor-positive breast cancer after endocrine therapy (review of TA295)
  - 37.1. The committee decision was based on consensus.
38. 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**
39. Thursday 29 September 2016 10:00am until 17:00pm at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT