

Technology Appraisal Committee Meeting (Committee A)

Minutes: [Confirmed]

Date and Time: Tuesday 8 January 2019, 10:05am – 5pm

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

Present:	1. Jane Adam, Chair 2. Dr Brian Shine 3. Mr Adrian Griffin 4. Dr Steve Edwards 5. Dr Alice Turner 6. Dr Graham Ash 7. Dr Jeremy Braybrooke 8. Professor John McMurray 9. Dr John Watkins 10. Dr Justin Daniels 11. Dr Mark Upton 12. Dr Minal Bakhai 13. Dr Mohit Sharma 14. Professor Olivia Wu 15. Ms Pamela Rees 16. Dr Paul Robinson 17. Mr Richard Ballerand 18. Dr Roger Whittaker 19. Mr Stephen Sharp 20. Dr Sumithra Maheswaran	Present for all notes Present for all notes Present for notes 1-15 & 35-46 Present for notes 16 to 46 Present for all notes Present for all notes Present for all notes Present for all notes Present for notes 1 to 15 and 35 to 46 Present for all notes Present for notes 1 to 15 Present for all notes Present for all notes Present for all notes Present for all notes Present for all notes
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In attendance:

Helen Knight	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
Gemma Barnacle	Project Manager, National Institute for Health and Care Excellence	Present for notes 1 to 15
Thomas Feist	Project Manager, National Institute for Health and Care Excellence	Present for notes 16 to 46
Portia Dodds	Technology Appraisal Administrator, National Institute for Health and Care Excellence	Present for notes 1 to 15

Marcia Miller	Technology Appraisal Administrator, National Institute for Health and Care Excellence	Present for notes 16 to 46
Kirsty Pitt	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 1 to 15
Sana Khan	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 16 to 34
Juliet Kenny	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 16 to 34
Eleanor Donegan	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 1 to 15
Zoe Charles	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 16 to 34

Non-public attendees:

Professor Andrew Wardley	Clinical expert - Consultant & MAHSC Honorary Chair in Breast Medical Oncology	Present for notes 1 to 12 and 35 to 43
Professor Peter Clark	NHS England CDF lead	Present for notes 1 to 15 and 35 to 43
Professor Carlo Palmieri	Clinical expert - Professor of Translational Oncology and Consultant Medical Oncologist	Present for notes 1 to 12
Professor Stephen Bain	Clinical Expert - Professor of Medicine (Diabetes) and Honorary Consultant Physician nominated by MSD	Present for notes 16 to 24 and 28 to 31
Dr John Wilding	Clinical expert - Professor of Medicine and Honorary Consultant Physician nominated by RCP and ABCD	Present for notes 16 to 24 and 28 to 31
Ms Holly Heath	Patient Expert - Senior Research and Policy Officer	Present for notes 1 to 12
Mariana Bacelar	ERG - BMJ Group	Present for notes 1 to 12
Dr Steve Edwards	ERG - BMJ Group	Present for notes 1 to 12
Charlotta Karner	ERG - BMJ Group	Present for notes 1 to 12
Norman Waugh	ERG - Warwick Evidence	Present for notes 16 to 24 and 28 to 31
Alison Davie	Company Reps - Eli Lilly and Company Limited	Present for notes 4 to 12
Rosalind Jarvis	Company reps - Eli Lilly	Present for notes 4 to 12

Basola Sowemimo	and Company Limited Company Reps - MSD	Present for notes 16 to 24 and 28 to 31
Dr Robert Chipperfield	Company Reps - MSD	Present for notes 16 to 24 and 28 to 31
Tom Loughran	Company Reps - Health Economist, Roche	Present for notes 35 to 43
Judy Fredriksson	Company Reps - Country Medical Manager Roche	Present for notes 35 to 43
Ana Uribe-Echeverry Adam Storror	NICE, Corporate Office NICE, Resource Impact Team	Present for all notes Present for all notes
Moni Choudhury	NICE, Analyst – Science Policy and Research	Present for notes 1 to 15
Jeanette Kusel	NICE, Director, Scientific Advice	Present for all notes
Joanna Richardson	NICE, TA	Present for notes 1 to 15
Caroline Bregman	NICE, TA	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 Abemaciclib with fulvestrant for treating advanced hormone-receptor positive, HER2-negative breast cancer after endocrine therapy [ID1339]
2. The Chair welcomed Richard Ballerand to his first meeting as a Lay member of the Appraisal Committee
3. Apologies were received from Mr Min Ven Teo and Dr Rita Faria

Appraisal of Abemaciclib with fulvestrant for treating advanced hormone-receptor positive, HER2-negative breast cancer after endocrine therapy [ID1339]

Part 1 – Open session

4. The Chair welcomed the invited experts: Miss Holly Heath, Professor Carlo Palmieri and Professor Andrew Wardley to the meeting and they introduced themselves to the Committee.
5. The Chair welcomed company representatives from Eli Lilly and Company Limited to the meeting.
6. The Chair asked all Committee members, to declare any relevant interests.
 - 6.1. No declaration of interests were made in relation to the appraisal topic.
 - 6.2. Dr Steve Edwards was unable to take part as a member of the Committee as he was participating as part of the ERG.
7. The Chair asked all NICE Staff to declare any relevant interests.
 - 7.1. No declaration of interests were made in relation to the appraisal topic.
8. The Chair asked all other invited guests (ERG and invited experts, not including observers) to declare their relevant interests.
 - 8.1. Miss Holly Heath declared a non-personal specific financial interest as Breast Cancer Care receives some funding from a range of pharma companies involved in this appraisal.
 - 8.2. Professor Carlo Palmieri declared a personal specific financial interest as he is involved in an Investigative study part funded by Pfizer and has also been a speaker and advisor on this trial and others
 - 8.3. Professor Andrew Wardley declared a personal specific financial interest as he has received fees being a speaker and advisor on this trial and others.
 - 8.3.1. It was agreed that all the declarations of interests made would not prohibit the experts from participating in this appraisal.
9. The Chair introduced the lead team, Dr Minal Bakhai, Dr Brian Shine and Ms Pamela Rees who gave presentations on the clinical effectiveness and cost effectiveness of Abemaciclib with fulvestrant for treating advanced hormone-receptor positive, HER2-negative breast cancer after endocrine therapy.

10. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
11. 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.
12. 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

13. Discussion on confidential information continued. This information was supplied by the company.
14. The Committee continued to discuss the clinical and cost effectiveness of Abemaciclib with fulvestrant for treating advanced hormone-receptor positive, HER2-negative breast cancer after endocrine therapy [ID1339].
 - 14.1. The committee decision was based on consensus.
15. The Committee instructed the technical team to prepare the Final Appraisal Document (FAD) in line with their decisions.

Appraisal of Ertugliflozin in triple therapy for treating type 2 diabetes [ID1160]

Part 1 – Open session

16. The Chair welcomed the invited experts: Professor Stephen Bain and Dr John Wilding to the meeting and they introduced themselves to the Committee.
17. The Chair welcomed company representatives from Merck Sharp and Dohme to the meeting.
18. The Chair asked all Committee members to declare any relevant interests
 - 18.1. Mr Adrian Griffin is employed by Johnson and Johnson who own a comparator medicine in this appraisal. He remained absent from the meeting.
 - 18.2. Professor John McMurray declared a personal pecuniary interest as he is a principal/co-principal investigator for two international trials, testing the efficacy and safety of dapagliflozin (AstraZeneca) in heart failure and another using bexagliflozin (Theracos) in patients with type 2 diabetes and cardiovascular disease or cardiovascular risk factors. He is also one of a group of lead investigators for local trials using empagliflozin (Boehringer Ingelheim) in patients with type 2 diabetes and heart failure. He remained absent from the meeting.
 - 18.3. Dr Paul Robinson declared a personal pecuniary interest as he is employed by shareholder of the manufacturer of the technology. He observed part one of the meeting and remained absent for the rest of the meeting.
19. The Chair asked all NICE Staff to declare any relevant interests.
 - 19.1. No declaration of interests were made in relation to this topic
20. The Chair asked all other invited guests (ERG and invited experts, not including observers) to declare their relevant interests.

- 20.1. Professor Stephen Bain declared a personal specific financial interest as he has done consultancy for MSD (European-Canadian advisory board).
- 20.2. Dr John Wilding declared a personal specific financial interest for lecture fees and consultancy for comparator companies: AstraZeneca, Boehringer, Novo Nordisk, Lilly, Sanofi and Takeda
 - 20.2.1. It was agreed the declarations made would not prohibit Professor Stephen Bain and Professor John Wilding from participation in this section of the meeting
21. The Chair introduced the lead team, Dr Graham Ash, Dr Olivia Wu and Ms Pamela Rees who gave presentations on the clinical effectiveness and cost effectiveness of Ertugliflozin in triple therapy for treating type 2 diabetes [ID1160]
22. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
23. 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.
24. 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

25. Discussion on confidential information continued. This information was supplied by the company.
26. The Committee continued to discuss the clinical and cost effectiveness of Ertugliflozin in triple therapy for treating type 2 diabetes [ID1160]
 - 26.1. The committee decision was based on consensus.
27. The Committee agreed to defer a decision on the content of the guidance section until the next appraisal meeting to allow for further clarification to be obtained from the company.

Appraisal of Ertugliflozin as monotherapy and in dual therapy for treating type 2 diabetes [ID1158] FTA

Part 1 – Open session

28. The Technical Analyst gave a presentation on the clinical effectiveness and cost effectiveness of Ertugliflozin as monotherapy and in dual therapy for treating type 2 diabetes [ID1158].
29. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
30. 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.

31. 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

32. Discussion on confidential information continued. This information was supplied by the company.
33. The Committee continued to discuss the clinical and cost effectiveness of Ertugliflozin in triple therapy for treating type 2 diabetes [ID1160]
 - 33.1. The committee decision was based on consensus.
34. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

Appraisal of pertuzunab for adjuvant treatment of early HER2-positive breast cancer [ID1192]

Part 1 – Open session

35. The Chair welcomed the invited expert Dr Andrew Wardley to the meeting and he introduced himself to the Committee.
36. The Chair welcomed company representatives from Roche to the meeting.
37. The Chair asked all Committee members to declare any relevant interests
 - 37.1. No declaration of interests were made in relation to this topic
38. The Chair asked all NICE Staff to declare any relevant interests.
 - 38.1. No declaration of interests were made in relation to this topic
39. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.
 - 39.1. Dr Andrew Wardley declared a personal specific financial interest for advisory and speaker engagements introducing a HER2 franchise. A non-personal specific interest was declared as a Dr Andrew Wardley has been a NCRI lead for research and development in HER2 practice.
 - 39.1.1. It was decided that the declaration would not prohibit Dr Andrew Wardley from participating in the meeting.
40. The Chair gave a presentation on the new information relating to the appraisal.
41. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
42. 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.
43. 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

44. Discussion on confidential information continued. This information was supplied by the company.
45. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

Date, time and venue of the next meeting

46. Tuesday 12 March 2019, 10am at the National Institute for Health and Care Excellence, 10 Spring Gardens, SW1A 2BU