Technology Appraisal Committee Meeting (Committee A)

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

Minutes: Confirmed

Date and Time: Tuesday 12 March 2019, 10:00 – 15:00

Present:	1. Dr Jan	e Adam (Chair)	Present for all notes
		n Shine (Vice-Chair)	Present for all notes
	3. Dr Gra	ham Ash	Present for all notes
4. Dr Jeremy Braybrooke		Present for all notes	
5. Dr Justin Daniels			Present for all notes
6. Dr Steve Edwards			Present for notes 11 to 15
7. Mr Adrian Griffin		Present for notes 1 to 10	
8. Dr Mohit Sharma		Present for all notes	
9. Mr Stephen Sharp		Present for all notes	
10. Dr Alice Turner			Present for all notes
11. Dr Mark Upton		Present for all notes	
12.Mrs Sarah Parry		Present for all notes	
13. Professor Olivia Wu		Present for all notes	
14. Ms Pamela Rees		Present for all notes	
	15. Dr Paul Robinson		Present for notes 1 to 10
		jer Whittaker	Present for all notes
17. Dr Sumithra Maheswaran		Present for all notes	
	18. Mr Min	Ven Teo	Present for notes 11 to 15
In attendance: Helen Knight		Programme Director, National Institute for Health and Care	Present for all notes
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Janet Robertson		Associate Director, National Institute for Health and Care Excellence	Present for all notes
Thomas Feist		Project Manager, National Institute for Health and Care Excellence	Present for all notes
Marcia Miller		Technology Administrator,	Present for all notes
Marcela Haasova		Technology Appraisal Technical Analyst,	Present for notes 1 to 10

Joanna Richardson	Technology Appraisal Technical Advisor,	Present for notes 1 to 10
Thomas Strong	Technology Appraisal , CDF HTA Advisor	Present for notes 1 to 10
Sana Khan	Technology Appraisal Technical Analyst,	Present for notes 11 to 15
Zoe Charles	Technology Appraisal Technical Advisor	Present for notes 11 to 15
Dr Steve Edwards	Evidence Review Group, Director of Health Technology Appraisals (BMJ)	Present for notes 1 to 7
Dr Samantha Barton	Evidence Review Group, Senior Research Fellow, Health Technology Appraisals (BMJ)	Present for notes 1 to 7
Dr Peter Cain	Evidence Review Group, Senior Research Fellow, Health Technology Appraisals (BMJ)	Present for notes 1 to 7
Professor Peter Clark	NHS England, CDF Clinical Lead	Present for notes for notes 1 to 10
Ms Holly Heath	Patient expert	Present for notes 1 to 7
Professor Robert Thomas	Clinical expert	Present for notes
Karen Ang	NICE, Scientific Advice	Present for notes 1 to 10
Ana Uribe Echeverry	NICE, Corporate Office	Present for notes
Mr Tony Heddon	NICE, Lay member appeal panel member	Present for notes 1 to 10
Adam Storrow	NICE, Resource Impact Assessment	Present for all notes
Ria Skelton	NICE, Appraisal Editors	Present for all notes

Minutes from the last meeting

1. The committee approved the minutes of the committee meeting held on Tuesday 8 January 2019.

Appraisal of Ribociclib in combination with fulvestrant for treating advanced hormone-receptor positive, HER2-negative breast cancer [ID1318]

Part 1 - Open session

- 2. The Chair welcomed the invited clinical and patient experts, Evidence Review Group (ERG) and representatives from Novartis.
- 3. The Chair asked all committee members, experts, ERG representatives and NICE staff present to declare any relevant interests.
 - 3.1. Dr Jeremy Braybrooke declared a non-financial interest as he has been a co-investigator on clinical trials with ribociclib and palbociclib in breast cancer.
 - 3.1.1. It was agreed that the declaration of interest made would not prohibit Dr Jeremy Braybrooke from participating in this appraisal.
 - 3.2. Ms Holly Heath declared a direct financial interest as Breast Cancer Now has received some funding from Novartis and other pharmaceutical companies involved in this appraisal (details are listed on their website). Breast Cancer Now does not receive funding for work on access to treatment.
 - 3.2.1. It was agreed that the declaration of interests made would not prohibit Ms Holly Heath from participating in this appraisal.
 - 3.3. Dr Steve Edwards did not take part as a member of the Committee as he was participating as a member of the Evidence Review Group.
- 4. The Chair introduced the lead team, Dr Paul Robinson, Mr Stephen Sharp and Ms Pamela Rees who gave presentations on the clinical effectiveness and cost effectiveness of Ribociclib in combination with fulvestrant for treating advanced hormone-receptor positive, HER2-negative breast cancer.
- 5. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
- 6. 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.
- 7. The Chair then thanked the and company representatives, evidence review group and experts for their attendance, participation and contribution to the appraisal and they left the meeting.

Part 2 - Closed session

- 8. Discussion on confidential information continued. This information was supplied by the company.
- 9. The Committee continued to discuss the clinical and cost effectiveness.
 - 9.1. The committee decision was based on consensus.
- 10. The Committee instructed the technical team to prepare the Appraisal Committee Document (ACD) in line with their decisions.

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

Part 1 - Open session

- 11. The Chair welcomed the company representatives from Merck Sharp and Dohme to the meeting.
- 12. The Chair asked all Committee members to declare any relevant interests
 - 12.1. Mr Adrian Griffin declared a direct financial interest as he is employed by Johnson and Johnson who own a comparator drug in this appraisal.
 - 12.1.1. It was agreed that the declaration of interests made would prohibit Mr Adrian Griffin from participating in this appraisal and he remained absent from the meeting.
 - 12.2. Professor John McMurray declared an indirect financial 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.
 - 12.2.1. It was agreed that the declaration of interests made would prohibit Professor John McMurray from participating in this appraisal and he remained absent from the meeting.
 - 12.3. Dr Paul Robinson declared a direct financial interest as he is employed by the company of the technology.
 - 12.3.1. It was agreed that the declaration of interests made would prohibit Dr Paul Robinson from participating in this appraisal he remained absent from the meeting.
- 13. The Chair asked all NICE Staff to declare any relevant interests.
 - 13.1. No declaration of interests were made in relation to this topic
- 14. The Chair gave a presentation on the new information provided by the company.
- 15. The Committee instructed the technical team to prepare the Final Appraisal Document (FAD) in line with their decisions.

Date, time and venue of the next meeting

Tuesday 9 April 2019, 10am at National Institute for Health and Care Excellence,
 Spring Gardens, London SW1A 2BU