

Technology Appraisal Committee Meeting (Committee [A])

Minutes: [confirmed]

Date and Time: Wednesday 5 July 2017

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

Present:	1. Chair Jane Adam 2. Professor Iain Squire 3. Dr Graham Ash 4. Dr Jeremy Braybrooke 5. Dr Justin Daniels 6. Mr Adrian Griffin 7. Dr Rachel Hobson 8. Dr Mohit Misra 9. Mrs Sarah Parry 10. Ms Pamela Rees 11. Dr Paul Robinson 12. Mr Mohit Sharma 13. Mr Stephen Sharp 14. Dr Brian Shine 15. Dr John Watkins 16. Dr Rita Faria	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 all notes
Janet Robertson	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
Marcia Miller	Technical Administrator,	Present for all notes

Marcela Haasova	Technical Analyst, National Institute for Health and Care Excellence	Present for all notes
Zoe Charles	Technical Adviser, National Institute for Health and Clinical Excellence	Present for all notes
Evidence Review Group		
Nasuh Buyukkaramikli	Kleijnen Systematic Reviews	Present for notes 1- 14
Rob Riemsma	Kleijnen Systematic Reviews	Present for notes 1-14
Saskia	Kleijnen Systematic Reviews	Present for notes 1 -14
Experts		
Dr Nick Turner	Consultant Medical Oncologist	Present for notes 1- 14
Melanie Sturtevant	Clinical Nominated by Novartis Patient expert nominated by Breast Cancer Now	Present for notes 1- 14
Non-public observers:		
Thomas Feist	NICE, Senior Guidelines Coordinator	Present for all notes
Isaac Hung	NICE Observer (Internship)	Present for all notes
Professor John McMurray	Committee Member	Present for all notes
Rebekah Pennington	Decision Support Unit	Present for notes 1 - 14

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 **Ribociclib in combination with an aromatase inhibitor for previously untreated advanced or metastatic hormone receptor-positive, HER2-negative breast cancer**
2. The Chair informed the Committee of the non-public observers at this meeting: Issac Hung, Thomas Feist, Rebekah Pennington and Joshua South
3. Apologies were received from Dr Ian Bernstein, Dr Andrew England, Dr Anne McCune, Dr Nerys Woolacott and Dr Olivia Wu.

Notes from the last meeting

4. The minutes from the last meeting were agreed

Appraisal of Ribociclib in combination with an aromatase inhibitor for previously untreated advanced or metastatic hormone receptor-positive, HER2-negative breast cancer

Part 1 – Open session

5. The Chair welcomed the invited experts: Dr Nicholas Turner, Melanie Sturvestant, Rob Riemsma, Saskia and Nasuh Buyukkaramikli to the meeting and they introduced themselves to the Committee.
6. The Chair welcomed company representatives from Novartis to the meeting.
7. The Chair asked all Committee members to declare any relevant interests
 - 7.1. Dr Jane Adam, Dr Graham Ash, Dr Justin Daniels, Mr Adrian Griffin, Dr Rachel Hobson, Dr Mohit Misra, Mrs Sarah Parry, Ms Pamela Rees, Dr Paul Robinson, Mr Mohit Sharma, Mr Stephen Sharp, Dr Brian Shine, Dr John Watkins and Dr Rita Faria 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 Ribociclib in combination with an aromatase

inhibitor for previously untreated advanced or metastatic hormone receptor-positive, HER2-negative breast cancer.

- 7.2. Dr Jeremy Braybrooke declared a non-personal specific financial interest as he is a co-investigator on clinical trials in breast cancer.
- 7.3. 7.2.1 It was agreed that this declaration would not prevent Dr Jeremy Braybrooke from participating in this section of the meeting,
- 7.4. Professor John McMurray declared a non-personal specific financial interest as he has received lecture fees and clinical trial funding from Novartis which was paid to his employer, Glasgow University. There has been no personal payment and work conducted was in the cardiovascular field and not in oncology.
 - 7.4.1 It was agreed that this declaration would not prevent Professor John McMurray from participating in this section of the meeting, however Professor John McMurray attended the meeting as a NICE observer.
- 7.5. Professor Iain Squired declared a non-personal specific financial interest as he has received honoraria for participation in advisory boards and education boards from the Novartis; he confirms that his institution has received support from the company for research. Both declaration are work in a disease area distinct from the appraisal.
 - 7.5.1 It was agreed that this declaration would not prevent Professor John McMurray from participating in this section of the meeting, however Professor John McMurray attended the meeting as a NICE observer.
- 7.6. Mr David Evans, declared a personal pecuniary financial interest as he holds shares in the comparator company AstraZeneca. It was agreed that this declaration would prevent Mr David Evans from participating in the meeting and for this reason he remained absent from the meeting

8. The Chair asked all NICE Staff to declare any relevant interests.

- 8.1. 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 Ribociclib in combination with an aromatase inhibitor for previously untreated advanced or metastatic hormone receptor-positive, HER2-negative breast cancer.
9. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.
- 9.1. Nasuh Buyukkaramikli and Rob Riemsma 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 Ribociclib in combination with an aromatase

inhibitor for previously untreated advanced or metastatic hormone receptor-positive, HER2-negative breast cancer.

- 9.2. Dr Nick Turner declared a personal non-specific financial interest as he has received advisory board Honoria from Novartis
 - 9.2.1. It was agreed that this declaration would not prevent Dr Nick Turner from participating in this section of the meeting
- 9.3. Melanie Sturtevant declared a personal non-specific financial interest as Breast Cancer Now has received some funding from Novartis. All funding received from pharma is available on the website.
 - 9.3.1. It was agreed that this declaration would not prevent Dr Nick Turner from participating in this section of the meeting

10. The Chair introduced the lead team, Dr Brian Shine, Dr Mohit Sharma and Ms Pamela Rees who gave presentations on the clinical effectiveness and cost effectiveness of Ribociclib in combination with an aromatase inhibitor for previously untreated advanced or metastatic hormone receptor-positive, HER2-negative breast cancer

Part 2a

11. Discussion on confidential information continued. This information was supplied by the company.
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 and company representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

Closed session

15. The Committee continued to discuss the clinical and cost effectiveness of Ribociclib in combination with an aromatase inhibitor for previously untreated advanced or metastatic hormone receptor-positive, HER2-negative breast cancer.
16. The Committee agreed to defer a decision on the content of the guidance section of the Appraisal Consultation Document (ACD) and DSU will be doing work to help the committee make a decision

Date, time and venue of the next meeting

17. Tuesday 8 August 2017 at 10am **NICE** Prince of Wales Suite, 10 Spring Garden SW1A 2BU