NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

# Technology Appraisal (Committee B) meeting minutes

 **Minutes:** Confirmed

**Date and time:** Wednesday 5 May 2021, 9:30am – 18:28pm

**Location:** via Zoom

## Committee members present:

1. Professor Amanda Adler (Chair) Present for all items
2. Dr Sanjeev Patel (Vice Chair) Present for all items
3. Dr Laura Bojke Present for items 1 to 5
4. Mr Mark Chapman Present for all items
5. Professor Iolo Doull Present for all items
6. Dr Megan John Present for items 1 to 5
7. Dr Nicholas Latimer Present for all items
8. Dr Rhiannon Owen Present for all items
9. Ms Anna Pracz Present for all items
10. Mr Peter Wheatley Price Present for all items
11. Dr Stephen Smith Present for all items
12. Dr Toby Smith Present for items 1 to 5
13. Professor Nicky Welton Present for all items
14. Mr Nigel Westwood Present for all items
15. Professor Sarah Wild Present for all items
16. Ms Mary Weatherstone Present for items 1 to 4
17. Dr Ed Wilson Present for all items
18. Mr Tony Wootton Present for all items

## NICE staff present:

Nicole Elliott, Associate Director Present for all items

Jo Ekeledo, Project Manager Present for all items

Lorna Dunning, Technical Advisor Present for items 1 to 4

Charlie Hewitt, Technical Advisor Present for items 1 to 4

Iordanis Sidiropoulos**,** Technical Advisor Present for items 1 to 4

Adam Brooke, Technical Advisor Present for item 5

Harsimran Sarpal, Technical Analyst Present for item 5

Ewa Rupniewska, Technical Advisor Present for items 6 and 7

Summaya Mohammed, Technical Analyst Present for items 5.1, 6 and 7

Hayley Garnett, Senior Medical Editor Present for items 1 to 4

Sarah Bromley, Senior Medical Editor Present for item 5

Ann Greenwood, Senior Medical Editor Present for items 6 and 7

Philip Williams, Business Analyst, RIA Present for all items

Heidi Livingstone, Public Involvement Advisor Present for items 1 to 4.1 and 5.1

Claire Hawksworth, Evidence Generation Present for items 1 to 5

Stevie Okoro, Technical Analyst - Commercial Risk Present for items 6 and 7

Catherine Pank, Assistant Project Manager Present for item 5.1 and 6.1

Lucinda Evans, Coordinator Present for items 1 to 4.1 and 6.1

Mira Patel, Coordinator Present for all items

Gemma Smith, Coordinator Present for 6 and 7

Sophie McHugh, Administrator Present for items 1 to 4 and 6 to 7

Daniel Greenwood, Assistant Administrator Present for item 5

## External group representatives present:

Joanne Lord, Director, Health Economist, Southampton Present for items 1 to 4.2

 HTA Centre

David Scott, Principal Research Fellow, Southampton Present for items 1 to 4.2

 HTA Centre

Charlotta Karner, HTA Analysis Manger, BMJ-TAG Present for item 5.1

Gemma Marceniuk, Associated Health Economist, Present for item 5.1

 BMJ-TAG

Dwayne Bowers, Research Fellow, Aberdeen HTA Present for item 6.1 and 6.2

Neil Scott, Research Fellow, Aberdeen HTA Present for item 6.1 and 6.2

## Professional experts present:

Professor Peter Clark, CDF Clinical Lead, NHSE&I Present for items 1 to 5

Dr Neil Rabin, clinical expert, Consultant Haematologist at UCL Present for items 1 to 4.1

 and Vice Chair of UK Myeloma Forum, nominated by

 UK Myeloma Forum

Dr Karthik Ramasamy, clinical expert, Consultant Haematologist, Present for items 1 to 4.1

 Oxford University Hospital, nominated by Janssen

Ms Shelagh McKinlay, patient expert, Head of Patient Advocacy at Present for items 1 to 4.1

 Myeloma UK, nominated by UK Myeloma Forum

Mrs Rosie Dill, patient expert, nominated by Myeloma UK Present for items 1 to 4.1

Professor John Bridgewater, clinical expert, Professor of Present for item 5.1

 Medical Oncology at UCL, nominated by BMS

Professor Richard Wilson, clinical expert, Professor of Present for item 5.1

 Gastrointestinal Oncology and Honorary Consultant in

 Medical Oncology, University of Glasgow and Beatson West

 of Scotland Cancer Centre, nominated by BMS

Ms Claire Donaghy, patient expert, Head of External Affairs Present for item 5.1

 (Devolved Nations) at Bowel Cancer UK, nominated by

 Bowel Cancer UK

Mr Tom Bartlett, patient expert, nominated by Bowel Cancer UK Present for item 5.1

## Observers present:

Jacoline Bouvy, Technical Director Present for items 1 to 4

Richard Diaz, Senior Technical Advisor Present for items 4.1.3. to 4.3.2.

Lucy Ingram, Administrator, NICE Present for items 1 to 5.1

Juliet Kenny, Senior HTA Adviser Present for items 1 to 4

Hugo Pedder, Senior Research Associate, Present for items 1 to 4

 Bristol Medical School

David Philippo, Senior Research Associate, Present for items 1 to 4

 Bristol Medical School

Pilar Pinilla-Dominguez, Principe Scientific Advisor Present for items 4.1.3. to 4.3.2.

### Introduction to the meeting

* 1. The Chair welcomed members of the committee and other attendees present to the meeting.
	2. The chair noted apologies from Dr Carlo Berti, Dr James Fotheringham, Dr Mark Glover, Dr Veline L’Esperance and Dr Stuart Williams.

### News and announcements

* 1. None.

### Minutes from the last meeting

* 1. The committee approved the minutes of the committee meetings held on 8 April 2021.

### Appraisal of Daratumumab in combination for untreated multiple myeloma when stem cell transplant is suitable [ID1510]

* 1. Part 1 – Open session
		1. The Chair welcomed the invited professional experts, external group representatives, members of the public and company representatives from Janssen.
		2. The Chair asked all committee members, professional experts, external group representatives and NICE staff present to declare any relevant interests in relation to the item being considered.
* Prior to the meeting, Mr Peter Wheatley-Price, committee member, declared a direct financial interest as his employer Takeda, manufacture ixazomib which used in combination with lenalidomide and dexamethasone, is indicated for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. This results in a potential conflict as they are therapeutically close and are in competition in one prior line. Takeda also have an ongoing trial for first line therapy for transplant ineligible patients as well as two other trials in multiple myeloma. It was agreed that these declarations did not prevent Mr Wheatley-Price from participating in this section of the meeting.
* Prior to the meeting, Dr Karthik Ramasamy, clinical expert, declared direct financial interests as he received research grants and speaker honoraria from Janssen. He also partook in a paid advisory board for Janssen. During the meeting, Dr Ramasamy declared further direct financial interests as he received speaker fees from Celgene, Amgen and Takeda. He also declared an indirect interest as his Trust received research grants from Janssen for running clinical trials. It was agreed that these declarations would not prevent Dr Ramasamy from providing expert advice to the committee.
* Dr Neil Rabin, clinical expert, declared several direct financial interests as he received financial support to attend conferences from BMS/Celgene, Janssen and Takeda. He was paid to speak at educational meetings by BMS/Celgene, Janssen, Takeda and Sanofi. Dr Rabin also partook in paid advisory boards for BMS/Celgene, Janssen, Takeda, Sanofi, Karyopharm and Amgen. Dr Rabin declared a non-financial professional and personal interest as he is an executive member of the UK Myeloma Forum. It was agreed that these declarations would not prevent Dr Rabin from providing expert advice to the committee.
* Ms Shelagh McKinlay, patient expert, declared indirect interests as her employer, Myeloma UK, receives funding from Janssen and other comparator companies. Janssen has also paid for Ms McKinlay to be involved with advisory boards. All monies go directly to Myeloma UK and Ms McKinlay does not personally benefit from these funds. It was agreed that these declarations would not prevent Ms McKinlay from providing expert advice to the committee.
* Prior to the meeting, Mr Hugo Pedder, observer, declared a direct financial interest as is he currently undertaking consultancy statistical work for Argenx on behalf of Clifton Insight, on a treatment for Myasthenia Gravis. The project involves writing a statistical analysis plan, analysing the data, and writing a report, and is expected to conclude in August 2021. Mr Pedder also declared non-financial professional and personal interests as he is currently a statistical advisor to the British Menopause Society and is a member of its Medical Advisory Council. Mr Pedder also undertakes advocacy work for ACT International. It was agreed these declarations would not prevent Mr Pedder from observing this section of the meeting.
* No further conflicts of interest were declared for this item.
	+ 1. The Chair introduced the lead team, Ms Mary Weatherstone, Mr Mark Chapman and Mr Tony Wootton, who gave presentations on the clinical effectiveness and cost effectiveness of Daratumumab in combination for untreated multiple myeloma when stem cell transplant is suitable [ID1510].
	1. Part 2a – Closed session (members of the public, company representatives and professional experts were asked to leave the meeting).
		1. The committee discussed confidential information submitted for this item.
	2. Part 2b – Closed session (external group representatives were asked to leave the meeting).
		1. The committee then agreed on the content of the Appraisal Consultation Document (ACD) or the Final Appraisal Determination (FAD). The committee decision was reached by consensus.
		2. The committee asked the NICE technical team to prepare the Appraisal Consultation Document (ACD) or Final Appraisal Determination (FAD) in line with their decisions.

### Appraisal of Nivolumab with ipilimumab for previously treated metastatic colorectal cancer with high microsatellite instability or mismatch repair deficiency [ID1332]

* 1. Part 1 – Closed session
		1. The Vice Chair welcomed the invited professional experts, external group representatives and company representatives from Bristol-Myers Squibb.

The Committee for Medicinal Products for Human Use (at the European Medicines Agency) had not yet given its regulatory opinion for Nivolumab with ipilimumab for previously treated metastatic colorectal cancer with high microsatellite instability or mismatch repair deficiency [ID1332] and as a consequence, the discussion took place in a closed part 2 session (part 2 sessions are closed to public observers).

* + 1. The Vice Chair asked all committee members, professional experts, external group representatives and NICE staff present to declare any relevant interests in relation to the item being considered.
* Professor John Bridgewater, clinical expert, declared a direct financial interest as he had partaken in paid advisory boards in the last 3 years, for pharmaceutical companies including BMS, in unrelated disease areas. Professor Bridgewater also declared that MSD have funded his attendance to a meeting around 5 years ago. It was agreed that these declarations would not prevent Professor Bridgewater from providing expert advice to the committee.
* Professor Richard Wilson, clinical expert, declared direct financial interests as he received honoraria for providing advice at health economics meetings with BMS in July and September 2020. BMS had also renumerated Professor Wilson with travel expenses and honorarium in 2017 for his participation in advisory boards. Professor Wilson also declared indirect interests as payments have been made to his institution where early and late phase cancer clinical trials, in both academic and commercial settings, are conducted. This includes studies using licensed and unlicensed agents owned by BMS. It was agreed that these declarations would not prevent Professor Wilson from providing expert advice to the committee.
* Ms Claire Donaghy, patient expert, declared indirect interests as her employer, Bowel Cancer UK, received funding from pharmaceutical companies, making up a total of less than 1% of their income. BMS was one of these companies and the funding was received over 12 months ago. It was agreed that this declaration did not prevent Ms Donaghy from providing expert advice to the committee.
* No further conflicts of interest were declared for this item.
	+ 1. The Vice Chair introduced the lead team, Dr Megan John, Mr Peter Wheatley-Price and Mr Tony Wootton, who gave presentations on the clinical effectiveness and cost effectiveness of Nivolumab with ipilimumab for previously treated metastatic colorectal cancer with high microsatellite instability or mismatch repair deficiency [ID1332].
	1. Part 2 – Closed session (company representatives, external group representatives and professional experts were asked to leave the meeting).
		1. The committee discussed confidential information submitted for this item.
		2. The committee then agreed on the content of the Appraisal Consultation Document (ACD) or the Final Appraisal Determination (FAD). The committee decision was reached by consensus.
		3. The committee asked the NICE technical team to prepare the Appraisal Consultation Document (ACD) or Final Appraisal Determination (FAD) in line with their decisions.
1. Appraisal of Fostamatinib for treating persistent or chronic immune thrombocytopenia [ID1087]
	1. Part 1 – Open session
		1. The Chair welcomed the invited professional experts, external group representatives, members of the public and company representatives from Grifols UK.
		2. The Chair asked all committee members, external group representatives and NICE staff present to declare any relevant interests in relation to the item being considered.
* Prior to the meeting, Dr Nicholas Latimer, committee member, declared a direct financial interest as he received payment from Pierre Fabre to provide advice on adjusting for treatment switching in the Beacon Study, investigating encorafenib+cetuximab plus or minus binimetinib in patients with BRAF V600E-mutant metastatic colorectal cancer. It was agreed that this declaration did not prevent Dr Latimer from participating in this section of the meeting.
* Prior to the meeting, Mr Peter Wheatley-Price, committee member, declared a direct financial interest as his employer, Takeda, have a compound in early clinical development (TAK-755) which will be indicated first for cTTP (around 2023) and then for iTTP (around 2024). It was agreed that this declaration did not prevent Mr Wheatley-Price from participating in this section of the meeting.
* Prior to the meeting, Dr Ed Wilson, committee member, declared an indirect interest as Roche, manufacturer of comparator drugs, is a client of his employer. His employer has not worked on any of the comparator drugs and Dr Wilson has not personally been involved in any work for Roche. It was agreed that this declaration did not prevent Dr Wilson from participating in this section of the meeting.
* No further conflicts of interest were declared for this item.
	+ 1. The Chair gave a presentation on the clinical and cost effectiveness of Fostamatinib for treating persistent or chronic immune thrombocytopenia [ID1087].
	1. Part 2a – Closed session (members of the public, company representatives and professional experts were asked to leave the meeting).
		1. The committee discussed confidential information submitted for this item.
	2. Part 2b – Closed session (external group representatives were asked to leave the meeting).
		1. The committee then agreed on the content of the Appraisal Consultation Document (ACD) or the Final Appraisal Determination (FAD). The committee decision was reached by consensus.
		2. The committee asked the NICE technical team to prepare the Appraisal Consultation Document (ACD) or Final Appraisal Determination (FAD) in line with their decisions.

### Date of the next meeting

The next meeting of the Technology Appraisal (Committee B) will be held on Wednesday 9 June 2021 and will start promptly at 9:30am.