

Technology Appraisal Committee Meeting (Committee C)

Minutes: **Confirmed**

Date and Time: Wednesday, 22 August 2018 10:00 – 17:00

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

Present:	1. Chair Prof Stephen O'Brien 2. Dr Alex Cale 3. Prof Andrew Renahan 4. David Bowen (D) 5. David Chandler 6. Gail Coster 7. John Hampson 8. Dr Judith Wardle 9. Malcolm Oswald 10. Prof Matt Stevenson 11. Michael Chambers 12. Dr Nigel Langford 13. Dr Paul Tappenden 14. Vice Chair Dr Peter Selby 15. Rachel Elliott (D) 16. Dr Richard Nicholas 17. Dr Robert Forsyth	Present for all notes Present for notes 1 to 22
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In attendance:

Helen Knight	Programme Director, National Institute for Health and Care Excellence	Present for all notes
Frances Sutcliffe	Associate Director, National Institute for Health and Care Excellence	Present for all notes
Stephanie Callaghan	Project Manager, National Institute for Health and Care Excellence	Present for all notes
Pratit Shah	Administrator, National Institute for Health and Care Excellence	Present for all notes

Alan Lamb	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 1 to 15
Nicola Hay	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 1 to 15
Abitha Senthinathan	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 16 to 23
Alexandra Filby	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 16 to 23 and notes 24 to 33
Julia Sus	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 24 to 33

Non-public attendees:

Mark Simmonds	ERG Representative	Present for notes 1 to 13
Matt Walton	ERG Representative	Present for notes 1 to 13
Rob Hogson	ERG Representative	Present for notes 1 to 13
Stephen Palmer	ERG Representative	Present for notes 16 to 33
Mark Corbett	ERG Representative	Present for notes 16 to 23
Ana Duarte	ERG Representative	Present for notes 16 to 23
Peter Clark	CDF Clinical Lead	Present for all notes
Rachael Hough	Clinical Expert	Present for notes 1 to 13
David Marks	Clinical Expert	Present for notes 1 to 13
Mike Brandon	Patient Expert	Present for notes 1 to 13
Claire Foreman	NHS Commissioning Expert	Present for notes 1 to 23
Phil Reynolds	Patient Expert	Present for notes 1 to 23
Sridhar Chaganti	Clinical Expert	Present for notes 1 to 23
Kate Cwynarski	Clinical Expert	Present for notes 1 to 23
Zack Pemberton- Whiteley	Patient Expert	Present for notes 1 to 23
Sachin Patel	Company representative	Present for notes 1 to 13
David Kuzan	Company representative	Present for notes 1 to 23
João Vieira	Company representative	Present for notes 16 to 23
Tiago Fonseca	Company representative	Present for notes 24 to 33
Simon Purcell	Company representative	Present for notes 24 to 33
Leslie Hayes	NICE Observer	Present for notes 1 to 33
Sally Doss	NICE Observer	Present for notes 1 to 23
Tom Strong	NICE Observer	Present for notes 1 to 23
Kirsty Pitt	NICE Observer	Present for notes 1 to 16
Carl Boswell	NICE Observer	Present for notes 1 to 16
Nicola Hay	NICE Observer	Present for notes 16 to 23

Pilar Pinilla-Dominguez	NICE Observer	Present for notes 16 to 23
Christopher Eatough	NICE Observer	Present for notes 1 to 16
Emmanuelle Kaltenbach	External observer	Present for notes 1 to 23
Hollie Melton	External observer	Present for notes 16 to 23

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 Tisagenlecleucel-T for treating relapsed or refractory B-cell acute lymphoblastic leukaemia in people aged 3 to 25 years [ID1167], Tisagenlecleucel-T for treating relapsed or refractory diffuse large B-cell lymphoma [ID1166] and Gemtuzumab ozogamicin for untreated acute myeloid leukaemia [ID982].
2. The Chair welcomed Dr Robert Forsyth to his first meeting as a member of the Appraisal Committee.
3. The Chair informed the Committee of the non-public observers at this meeting: Carl Boswell, Sally Doss, Christopher Eatough, Nicola Hay, Leslie Hayes, Pilar Pinilla-Dominguez, Kirsty Pitt and Tom Strong.
4. Apologies were received from Mr Kamal Balakrishnan, Dr Prithwiraj Das, Dr Natalie Hallas, Prof Andrea Manca, Dr Rubin Minas, Dr Derek Ward and Prof Robert Walton.

Appraisal of Tisagenlecleucel-T for treating relapsed or refractory B-cell acute lymphoblastic leukaemia in people aged 3 to 25 years [ID1167]

Part 1 – Open session

5. The Chair welcomed the invited experts: Mike Brandon, Peter Clark, Claire Foreman, Rachael Hough, David Marks and Phil Reynolds 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. David Bowen, Alex Cale, David Chandler, Gail Coster, Rachael Elliott, Rob Forsyth, John Hampson, Nigel Langford, Richard Nicholas, Malcolm Oswald, Matt Stevenson, Paul Tappenden and Judith Wardle 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 Tisagenlecleucel-T for treating relapsed or refractory B-cell acute lymphoblastic leukaemia in people aged 3 to 25 years [ID1167].
 - 7.2. Stephen O'Brien declared a non-personal specific non-financial interest related to his involvement in research at Newcastle University, for the

SPIRIT 2 Trial in CML funded by BMS a comparator company. In addition his organisation is bidding to provide CAR-T cell therapy

- 7.3. Michael Chambers declared a non-personal non-specific financial interest as he provided advice to a comparator company, Sanofi Pharmaceuticals about modelling effectiveness of a drug on an unrelated topic.
- 7.4. Peter Selby declared a non-personal non-specific financial interest as his organisation is bidding to provide CAR-T cell therapy.
- 7.5. Andrew Renahan declared a non-personal non-specific financial interest as his organisation is bidding to provide CAR-T cell therapy.
 - 7.5.1. It was agreed that these declarations would not prevent the members from participating in this section of 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 Tisagenlecleucel-T for treating relapsed or refractory B-cell acute lymphoblastic leukaemia in people aged 3 to 25 years [ID1167].

9. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.

- 9.1. Rachel Hough declared a non-personal specific non-financial interest as she participated as an advisor to Novartis in clinical trials.
- 9.2. David Marks declared a non-personal specific non-financial interest as he participated as a clinical expert to Novartis in CAR-T trials.
- 9.3. Mike Brandon declared a personal specific non-financial interest as he is a CAR-t patient and he participated in interviews by Novartis.
 - 9.3.1. It was agreed that these declarations would not prevent the guests from participating in this section of the meeting.

10. The Chair introduced the lead team Alex Cale, Judith Wardle and Matt Stevenson who gave presentations on the clinical effectiveness and cost effectiveness of Tisagenlecleucel-T for treating relapsed or refractory B-cell acute lymphoblastic leukaemia in people aged 3 to 25 years [ID1167].

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

12. 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.

13. 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

14. Discussion on confidential information continued. This information was supplied by the company.
15. The Committee continued to discuss the clinical and cost effectiveness of Tisagenlecleucel-T for treating relapsed or refractory B-cell acute lymphoblastic leukaemia in people aged 3 to 25 years [ID1167].

Appraisal of Tisagenlecleucel-T for treating relapsed or refractory diffuse large B-cell lymphoma [ID1166]

Part 1 – Open session

16. The Chair welcomed the invited experts: Peter Clark, Sridhar Chaganti, Kate Cwynarski, Claire Foreman, Zack Pemberton-Whitney and Claire Reynolds to the meeting and they introduced themselves to the Committee.
17. The Chair welcomed company representatives from Novartis to the meeting.
18. The Chair asked all Committee members to declare any relevant interests
 - 18.1. David Bowen, Alex Cale, David Chandler, Gail Coster, Rachael Elliott, Rob Forsyth, John Hampson, Nigel Langford, Malcolm Oswald, Matt Stevenson, Paul Tappenden and Judith Wardle 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 Tisagenlecleucel-T for treating relapsed or refractory diffuse large B-cell lymphoma [ID1166].
 - 18.2. Stephen O'Brien declared a non-personal specific financial interest related to his involvement in research at Newcastle University, for the SPIRIT 2 Trial in CML funded by BMS a comparator company. In addition his organisation is bidding to provide CAR-T cell therapy.
 - 18.3. Michael Chambers declared a non-personal non-specific financial interest as he participated in advisory boards on behalf of York Health Economics for Roche, a comparator company in an unrelated area.
 - 18.4. Peter Selby declared a non-personal non-specific financial interest as his organisation is bidding to provide CAR-T cell therapy.
 - 18.5. Andrew Renahan declared a non-personal non-specific financial interest as his organisation is bidding to provide CAR-T cell therapy.
 - 18.6. Richard Nicholas declared a personal non-specific non-financial interest as he is participating in a trial committee with Roche, a comparator company in an unrelated area.

- 18.6.1. It was agreed that these declarations would not prevent the members from participating in this section of the meeting.
- 18.7. The Chair asked all NICE Staff to declare any relevant interests.
- 18.8. 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 Tisagenlecleucel-T for treating relapsed or refractory diffuse large B-cell lymphoma [ID1166].
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 Tisagenlecleucel-T for treating relapsed or refractory diffuse large B-cell lymphoma [ID1166].
20. The Chair introduced the lead team - Alex Cale, Matt Stevenson, Judith Wardle, who gave presentations on the clinical effectiveness and cost effectiveness of Tisagenlecleucel-T for treating relapsed or refractory diffuse large B-cell lymphoma [ID1166].
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.

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

23. Discussion on confidential information continued. This information was supplied by the company.
24. The Committee continued to discuss the clinical and cost effectiveness of Tisagenlecleucel for treating relapsed or refractory diffuse large B-cell lymphoma after 2 or more systemic therapies [ID1166].

Appraisal of Gemtuzumab ozogamicin for untreated acute myeloid leukaemia [ID982]

Part 1 – Open session

25. The Chair welcomed the invited experts: Peter Clark to the meeting and they introduced themselves to the Committee.
26. The Chair welcomed company representatives from Pfizer to the meeting.
27. The Chair asked all Committee members to declare any relevant interests
 - 27.1. Alex Cale, Andrew Renahan, David Chandler, Gail Coster, John Hampson, Judith Wardle, Michael Chambers, Malcolm Oswald, Matt Stevenson, Nigel Langford, Peter Selby, Paul Tappenden, Richard Nicholas, Stephen O'Brien 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 Gemtuzumab ozogamicin for untreated acute myeloid leukaemia [ID982].
 - 27.2. David Bowen declared a personal specific financial interest as he was a co-author of a publication for a clinical trial involving Gemtuzumab in low intensity therapy for acute myeloid leukaemia.
 - 27.3. Rachel Elliott declared a non-personal non-specific financial interest as she was paid a consultancy fee by Pfizer at an EU Innovation Summit
 - 27.3.1. It was agreed that these declarations would not prevent the members from participating in this section of the meeting.
28. The Chair asked all NICE Staff to declare any relevant interests.
 - 28.1. 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 Gemtuzumab ozogamicin for untreated acute myeloid leukaemia [ID982].
29. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.
 - 29.1. 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 Gemtuzumab ozogamicin for untreated acute myeloid leukaemia [ID982].
30. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
31. 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.

32. 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

33. Discussion on confidential information continued. This information was supplied by the company.
34. The Committee continued to discuss the clinical and cost effectiveness of Gemtuzumab ozogamicin for untreated acute myeloid leukaemia [ID982].
 - 34.1. 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

34. Thursday 27 September 2018 from 10am to 5pm at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.