INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, July 25, 2025**
Time:	8:00 am US Mountain Time
Location:	Zoom Teleconference
Institution:	Banner Research, Gilbert, AZ
Principal Investigator:	**Matthew Ulrickson, MD**
Protocol:	A2 Biotherapeutics, Inc., **A2B694-101**
NCT Number:	NCT06051695
Meeting Type:	Continuing Review of Protocol and Site
Title:	EVEREST-2: A Seamless Phase 1/2 Study to Evaluate the Safety and Efficacy of A2B694, an Autologous Logic-gated Tmod™ CAR T, in Heterozygous HLA-A*02 Adults with Recurrent Unresectable, Locally Advanced, or Metastatic Solid Tumors That Express MSLN and Have Lost HLA-A*02 Expression

1. Call to order:

The Meeting was called to order at 8:14 am US Mountain Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Four voting members were present, including two local members unaffiliated with the institution. Also present were six Institutional Representatives and IBC Services staff. The Chair declared that a quorum was present.

4. Conflict of Interest:

The Chair requested that voting members report any conflict of interest regarding this meeting. No conflicts of interest were reported.

5. Public posting:

An Institutional Representative confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

6. Approval of previous meeting minutes:

Minutes Approved - YES: 4 NO: 0 ABSTAIN: 0

7. Review of proposed research:

The Chair provided an overview of the protocol and status of the study.

The Chair provided an overview of changes since the last review.

8. Determination for biosafety level and period of IBC oversight:

The Committee previously determined that **BSL-2 containment facilities and practices** are required for A2B694, since it consists of primary human cells modified with a recombinant lentiviral vector. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **3 months after the last subject's last dose locally of A2B694**, provided all other biosafety criteria required for study closure are met. The Committee reaffirmed this determination.

9. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4 NO: 0 ABSTAIN: 0

10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Point of Discussion:

1. An Institutional Representative confirmed that biohazard-labeled red bags are placed in red biohazardous waste containers, which should be labeled with a biohazard symbol. The Committee recommended that the Photos document be revised to indicate biohazard waste containers are labeled. The Committee recommended that the Institution submit an updated/representative photo to IBC Services of a biohazard-labeled biohazardous waste container available in the dosing room.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representatives.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 8:20 am US Mountain Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Version 2.0, dated 12-18-2024
Investigator's Brochure, Edition 2.0, dated 11-04-2024
Investigational Product Manual, Version 2.0, dated 03-20-2025
Research Modification Evaluation, Protocol, Version 2.0
Research Modification Evaluation, Investigator's Brochure. Edition 2.0
Research Modification Evaluation, Investigational Product Manual, Version 2.0
Biological Risk Assessment and Summary, updated 04-22-2025
Site Map, BGMC 2nd Floor, dated 08-28-2023
Site Map, BGMC 5th Floor, dated 08-15-2023
Site Map, BMDACC 3rd Floor, dated 05-12-2025
Site Map, BMDACC Infusion Suite, dated 05-12-2025
Site Inspection Checklist, T Cell Studies, expires 03-06-2027, updated 06-12-2025
Photos, T Cell and Non-T Cell, BMDACC Infusion Area, dated 08-28-2024
Photos, T Cell Studies, BMDACC and BGMC Dosing Rooms, dated 10-07-2024
Photos, T Cell Studies, BMDACC, Cell Therapy Lab, dated 05-02-2025
Biohazard Sign, Genetically Modified Human Cells, dated 06-12-2025
SOP Addendum, Biosafety for Autologous Cells, dated 07-18-2025
SOP, Biosafety for Genetically Modified Human Cells, dated 06-12-2025
Training, Shipping Certifications, expire 10-02-2025, 12-01-2025
CRRF, dated 04-04-2025
Prior Meeting Minutes, Initial, dated 07-09-2024

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, July 25, 2025**
Time:	8:00 am US Mountain Time
Location:	Zoom Teleconference
Institution:	Banner Research, Gilbert, AZ
Principal Investigator:	**Matthew Ulrickson, MD**
Protocol:	Kite Pharma, Inc., **KT-US-471-0140**
NCT Number:	NCT05776160
Meeting Type:	Continuing Review of Protocol and Site
Title:	Expanded access study for the treatment of patients with commercially out-of-specification Axicabtagene Ciloleucel.

1. Call to order:

The Meeting was called to order at 8:00 am US Mountain Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Four voting members were present, including two local members unaffiliated with the institution. Also present were five Institutional Representatives and IBC Services staff. The Chair declared that a quorum was present.

4. Conflict of Interest:

The Chair requested that voting members report any conflict of interest regarding this meeting. No conflicts of interest were reported.

5. Public posting:

An Institutional Representative confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

6. Approval of previous meeting minutes:

Minutes Approved - YES: 4 NO: 0 ABSTAIN: 0

7. Review of proposed research:

The Chair provided an overview of the protocol and status of the study.

The Chair provided an overview of changes since the last review.

8. Determination for biosafety level and period of IBC oversight:

The Committee previously determined that **BSL-2 containment facilities and practices** are required for KTE-C19, since it consists of autologous T cells modified by a gammaretroviral vector. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **3 months after the last subject's last dose of KTE-C19 locally**, provided all other criteria for study closure are met. The Committee reaffirmed this determination.

9. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4 NO: 0 ABSTAIN: 0

10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Point of Discussion:

1. An Institutional Representative confirmed that biohazard-labeled red bags are placed in red biohazardous waste containers, which should be labeled with a biohazard symbol. The Committee recommended that the Photos document be revised to indicate biohazard waste containers are labeled. The Committee recommended that the Institution submit an updated/representative photo to IBC Services of a biohazard-labeled biohazardous waste container available in the dosing room.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representatives.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 8:09 am US Mountain Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Version 1.0, dated 03-31-2023
Investigator's Brochure, Edition 15.0, dated 01-08-2025
Investigational Product Manual, Version 5.0, dated 04-07-2025
Research Modification Evaluation, Investigational Product Manual, Version 4.0
Research Modification Evaluation, Investigational Product Manual, Version 5.0
Research Modification Evaluation, Investigator's Brochure, Edition 15.0
Biological Risk Assessment and Summary, updated 05-01-2025
Site Map, BGMC 2nd Floor, dated 08-28-2023
Site Map, BGMC 5th Floor, dated 08-15-2023
Site Map, BMDACC 3rd Floor, dated 05-12-2025
Site Map, BMDACC Infusion Suite, dated 05-12-2025
Site Inspection Checklist, T Cell Studies, expires 03-06-2027, updated 06-12-2025
Photos, T Cell and Non-T Cell, BMDACC Infusion Area, dated 08-28-2024
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Photos, T Cell Studies, BMDACC, Cell Therapy Lab, dated 05-02-2025
Biohazard Sign, Genetically Modified Human Cells, dated 06-12-2025
SOP Addendum, Biosafety for Autologous Cells, dated 07-18-2025
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Training, Shipping Certifications, expire 10-02-2025, 12-01-2025
CRRF, dated 04-08-2025
Prior Meeting Minutes, Continuing, dated 07-09-2024

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, July 25, 2025**
Time:	8:00 am US Mountain Time
Location:	Zoom Teleconference
Institution:	Banner Research, Gilbert, AZ
Principal Investigator:	**Matthew Ulrickson, MD**
Protocol:	Kite Pharma, Inc., **KT-US-472-0141**
NCT Number:	NCT05776134
Meeting Type:	Continuing Review of Protocol and Site
Title:	Expanded access study for the treatment of patients with commercially out-of-specification Brexucabtagene Autoleucel.

1. Call to order:

The Meeting was called to order at 8:10 am US Mountain Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Four voting members were present, including two local members unaffiliated with the institution. Also present were six Institutional Representatives and IBC Services staff. The Chair declared that a quorum was present.

4. Conflict of Interest:

The Chair requested that voting members report any conflict of interest regarding this meeting. No conflicts of interest were reported.

5. Public posting:

An Institutional Representative confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

6. Approval of previous meeting minutes:

Minutes Approved - YES: 4 NO: 0 ABSTAIN: 0

7. Review of proposed research:

The Chair provided an overview of the protocol and status of the study.

The Chair provided an overview of changes since the last review.

8. Determination for biosafety level and period of IBC oversight:

The Committee previously determined that **BSL-2 containment facilities and practices** are required for KTE-X19, since it consists of autologous T cells modified by a gammaretroviral vector. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **3 months after the last subject's last dose of KTE-X19 locally**, provided all other criteria for study closure are met. The Committee reaffirmed this determination.

9. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4 NO: 0 ABSTAIN: 0

10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Point of Discussion:

1. An Institutional Representative confirmed that biohazard-labeled red bags are placed in red biohazardous waste containers, which should be labeled with a biohazard symbol. The Committee recommended that the Photos document be revised to indicate biohazard waste containers are labeled. The Committee recommended that the Institution submit an updated/representative photo to IBC Services of a biohazard-labeled biohazardous waste container available in the dosing room.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representatives.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 8:13 am US Mountain Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Original, dated 05-12-2022
Investigator's Brochure, Edition 9.0, dated 10-11-2024
Investigational Product Manual, Version 5.0, dated 04-07-2025
Research Modification Evaluation, Investigational Product Manual, Version 4.0
Research Modification Evaluation, Investigational Product Manual, Version 5.0
Research Modification Evaluation, Investigator's Brochure, Edition 9.0
Biological Risk Assessment and Summary, updated 05-01-2025
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Site Map, BGMC 5th Floor, dated 08-15-2023
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