INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Tuesday, August 12, 2025**
Time:	9:00 am US Mountain Time
Location:	Zoom Teleconference
Institution:	Banner Research, Gilbert, AZ
Principal Investigator:	**Sumit Madan, MD**
Protocol:	Kite Pharma, Inc., **KT-US-679-0788**
NCT Number:	NCT06413498
Meeting Type:	Continuing Review of Protocol and Site
Title:	A Phase 3, Randomized, Open-Label Study to Compare the Efficacy and Safety of Anitocabtagene Autoleucel Versus Standard of Care Therapy in Participants With Relapsed/Refractory Multiple Myeloma

1. Call to order:

The Meeting was called to order at 9:01 am US Mountain Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Five 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: 5 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 anitocabtagene autoleucel, since it consists of genetically modified primary human cells. 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 anitocabtagene autoleucel locally**, provided that other biosafety criteria for study closure are also 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: 5 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. The Committee discussed that the biohazardous waste containers in the BMDACC and BGMC dosing areas have not yet been labeled with a biohazard symbol as previously recommended. An Institutional Representative confirmed that this issue has been escalated to leadership but that no changes have yet been implemented. The Committee recommended again that all biohazardous waste containers be labeled with a biohazard symbol.

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: 5 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 9:12 am US Mountain Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Amendment 1.0, dated 02-27-2025
Investigator's Brochure, Edition 2, dated 04-09-2025
Investigational Product Manual, Version 3.0, dated 04-07-2025
Research Modification Evaluation, Protocol, Amendment 1.0
Research Modification Evaluation, Investigator's Brochure, Edition 2
Research Modification Evaluation, Investigational Product Manual, Version 3.0
Research Modification Evaluation, Investigational Product Manual, Version 2.0
Biological Risk Assessment and Summary, updated 06-16-2025
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 07-30-2025
Photos, T Cell Studies, BMDACC, Cell Therapy Lab, dated 05-02-2025
Biohazard Sign, Genetically Modified Human Cells, dated 06-12-2025
SOP, Biosafety for Genetically Modified Human Cells, dated 06-12-2025
SOP Addendum, Biosafety for Autologous Cells, dated 07-18-2025
Training, Shipping Certifications, expire 10-02-2025, 12-01-2025
CRRF, dated 05-05-2025
Prior Meeting Minutes, Initial, dated 08-19-2024

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Tuesday, August 12, 2025**
Time:	9:00 am US Mountain Time
Location:	Zoom Teleconference
Institution:	Banner Research, Gilbert, AZ
Principal Investigator:	**Gary Walker, MD**
Protocol:	MeiraGTx, LLC, **MGT-AQP1-201**
NCT Number:	NCT05926765
Meeting Type:	Continuing Review of Protocol and Site
Title:	A Randomized, Double-Blind, Placebo-Controlled Study to Determine the Efficacy and Safety of AAV2-hAQP1 Gene Therapy in Participants with Radiation-Induced Late Xerostomia

1. Call to order:

The Meeting was called to order at 9:19 am US Mountain Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Five 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-1 containment facilities and practices plus Standard Precautions** are required for AAV2-hAQP1, since it consists of an AAV vector being administered by injection in a clinical setting. 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 AAV2-hAQP1 locally**, provided that other biosafety criteria for study closure are also 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: 5 NO: 0 ABSTAIN: 0

10. Review of proposed facilities and practices:

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

Points of Discussion:

1. The Committee recommended that the Biohazardous Waste Disposal section in the Biosafety SOP be reformatted to Section 4 and that subsequent sections be revised accordingly.
2. The Committee recommended that all biohazardous waste containers be labeled with a biohazard symbol.
3. The Committee recommended that the photos of the 70% isopropyl alcohol be removed from the BMDACC, 3rd Floor Freezer Corridor & Investigational Pharmacy document since it should not be used as a primary disinfectant.

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: 5 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 9:26 am US Mountain Time.

15. Post-meeting notes: The IBC Chair noted after the meeting that all biohazardous waste containers shown in the Photos document appear to be labeled with a biohazard symbol.

Documents reviewed:

Agenda
Protocol Version 5.0, dated 05-06-2025
Investigator's Brochure, Version 7.0, dated 04-11-2025
Pharmacy Manual, Version 7.0, dated 05-09-2025
Research Modification Evaluation, Protocol Version 5.0
Research Modification Evaluation, Investigator's Brochure, Version 7.0
Research Modification Evaluation, Pharmacy Manual, Version 6.0
Research Modification Evaluation, Pharmacy Manual, Version 7.0
Biological Risk Assessment and Summary, updated 05-16-2025
Site Map, BGMC 2nd Floor Imaging, dated 10-11-2022
Site Map, BGMC 5th Floor, dated 08-15-2023
Site Map, BMDACC 2nd Floor, dated 10-11-2022
Site Map, BMDACC 3rd Floor, dated 05-12-2025
Site Map, BMDACC Infusion Suite, dated 05-12-2025
Site Inspection Checklist, Non-T Cell Studies, expires 03-05-2027, updated 08-04-2025
Photos, Non-T Cell Studies, BGMC Dosing Rooms, dated 02-12-2025
Photos, Non-T Cell Studies, BMDACC, Dosing Rooms, dated 02-12-2025
Photos, Non-T Cell Studies, Storage and Preparation, dated 05-13-2025
Photos, T Cell and Non-T Cell, BMDACC Infusion Area, dated 08-28-2024
Biohazard Sign, AAV2-hAQP1, dated 07-26-2023
Biological Safety Cabinet Certifications, BMDACC Pharmacy, expire 11-2025
SOP, Biosafety for AAV2-hAQP1, dated 04-28-2025
Training, Shipping Certifications, expire 10-02-2025, 12-01-2025
CRRF, dated 05-06-2025, updated 08-06-2025
Prior Meeting Minutes, Continuing, dated 08-27-2024

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Tuesday, August 12, 2025**
Time:	9:00 am US Mountain Time
Location:	Zoom Teleconference
Institution:	Banner Research, Gilbert, AZ
Principal Investigator:	**Fade Mahmoud, MD, FACP**
Protocol:	Replimune, Inc., **RP1-104**
NCT Number:	NCT06264180
Meeting Type:	Continuing Review of Protocol and Site
Title:	A Randomized, Controlled, Multicenter, Phase 3 Clinical Study Comparing Vusolimogene Oderparepvec in Combination with Nivolumab Versus Treatment of Physician's Choice in Patients with Advanced Melanoma That Has Progressed on an Anti-PD-1 and an Anti-CTLA-4 Containing Treatment Regimen (IGNYTE-3)

1. Call to order:

The Meeting was called to order at 9:12 am US Mountain Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Five 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: 5 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 RP1 since it is based on a recombinant herpes simplex virus-1 administered in a clinical setting. 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 RP1 locally**, provided that other biosafety criteria for study closure are also 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: 5 NO: 0 ABSTAIN: 0

10. Review of proposed facilities and practices:

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

Points of Discussion:

1. The Committee recommended that all biohazardous waste containers be labeled with a biohazard symbol.
2. The Committee recommended that the photos of the 70% isopropyl alcohol be removed from the BMDACC, 3rd Floor Freezer Corridor & Investigational Pharmacy document since it should not be used as a primary disinfectant.

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 9:19 am US Mountain Time.

15. Post-meeting notes: The IBC Chair noted after the meeting that all biohazardous waste containers shown in the Photos document appear to be labeled with a biohazard symbol.

Documents reviewed:

Agenda
Protocol, Version 2.0, dated 05-03-2024
Protocol Clarification Letter, dated 11-14-2024
Protocol Clarification Letter #2, dated 02-05-2025
Investigator's Brochure, Edition 10.0, dated 02-19-2025
Pharmacy and Administration Manual, Version 1.0, dated 02-28-2024
Instructions For Patients After Injection, dated 04-12-2024
Intratumoral Injection Manual, Version 2.0, dated 08-30-2022
Research Modification Evaluation, Investigator's Brochure, Edition 10.0
Research Modification Evaluation, Protocol Clarification Letter
Research Modification Evaluation, Protocol Clarification Letter #2
Biological Risk Assessment and Summary, updated 03-10-2025
Site Map, BGMC 2nd Floor Imaging, dated 10-11-2022
Site Map, BGMC 5th Floor, dated 08-15-2023
Site Map, BMDACC 2nd Floor, dated 10-11-2022
Site Map, BMDACC 3rd Floor, dated 05-12-2025
Site Map, BMDACC Infusion Suite, dated 05-12-2025
Site Inspection Checklist, Non-T Cell Studies, expires 03-05-2027, updated 08-04-2025
Photos, Non-T Cell Studies, BGMC Dosing Rooms, dated 02-12-2025
Photos, Non-T Cell Studies, BMDACC, Dosing Rooms, dated 02-12-2025
Photos, Non-T Cell Studies, Storage and Preparation, dated 05-13-2025
Photos, T Cell and Non-T Cell, BMDACC Infusion Area, dated 08-28-2024
Biohazard Sign, RP1, dated 08-23-2024
Biological Safety Cabinet Certifications, BMDACC Pharmacy, expire 11-2025
SOP, Biosafety for RP1, dated 08-27-2024
Training, Shipping Certifications, expire 10-02-2025, 12-01-2025
CRRF, dated 05-07-2025
Prior Meeting Minutes, Initial, dated 08-27-2024