INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Tuesday, June 24, 2025**
Time:	8:00 am Arizona Time
Location:	Zoom Teleconference
Institution:	Banner Research, Gilbert, AZ
Principal Investigator:	**Matthew Ulrickson, MD**
Protocol:	Autolus, Inc., **AUTO1-OS1**
NCT Number:	NCT06799221
Meeting Type:	Initial Review of Protocol and Site
Title:	Expanded Access Program (EAP) for Obecabtagene Autoleucel (obe-cel) Out-of-specification (OOS) in Adult Patients with Acute Lymphoblastic Leukemia

1. Call to order:

The Meeting was called to order at 8:00 am Arizona 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. Review of proposed research:

The Chair provided an overview of the protocol.

The Chair provided an overview of the biosafety risk assessment for the protocol.

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

The Committee determined that **BSL-2 containment facilities and practices** are required for obe-cel since it consists of primary human cells modified using a recombinant, replication-defective lentiviral vector.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of obe-cel locally**, provided that all other criteria for study closure are also met.

8. 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

9. Review of Principal Investigator qualifications:

The Committee reviewed and accepted the qualifications of the Principal Investigator.

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 Biosafety SOP Addendum Section 3.4.1. be revised to indicate that obecel is administered via gravity flow infusion.
2. An Institutional Representative confirmed that the biological safety cabinets (BSCs) were recently recertified and that the updated reports will be provided to IBC Services once they are available.

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 Arizona Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Version 1.0, dated 11-22-2024
Investigator's Brochure, Version 6.0, dated 10-23-2024
Prescribing Information, dated 11-2024
Biological Risk Assessment and Summary, dated 02-13-2025
Site Map, BMDACC Infusion Suite, dated 05-12-2025
Site Map, BGMC 2nd Floor, dated 08-28-2023
Site Map, BMDACC 3rd Floor, dated 05-12-2025
Site Map, BGMC 5th Floor, dated 08-15-2023
Site Inspection Checklist, T Cell Studies, expires 03-06-2027, updated 06-12-2025
Photos, T Cell Studies, BMDACC and BGMC Dosing Rooms, dated 10-07-2024
Photos, T Cell and Non-T Cell, BMDACC Infusion Area, dated 08-28-2024
Photos, T Cell Studies, BMDACC, Cell Therapy Lab, dated 05-02-2025
Biohazard Sign, Genetically Modified Human Cells, dated 06-12-2025
Biological Safety Cabinet Certifications, Cell Therapy Lab, expires 06-2025
SOP, Biosafety for Genetically Modified Human Cells, dated 06-12-2025
SOP Addendum, Biosafety for Autologous Cells, dated 06-12-2025
Training, Shipping Certifications, expire 10-02-2025, 12-01-2025
CV, Ulrickson, M., signed 04-02-2024

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Tuesday, June 24, 2025**
Time:	8:00 am Arizona Time
Location:	Zoom Teleconference
Institution:	Banner Research, Gilbert, AZ
Principal Investigator:	**Ambuga Badari, MD**
Protocol:	Juno Therapeutics, Inc., a Bristol-Myers Squibb Company, **CA0881000**
NCT Number:	NCT06297226
Meeting Type:	Continuing Review of Protocol and Site
Title:	A Phase 2, Open-Label, Multicenter Study of Arlocabtagene Autoleucel (BMS-986393), a GPRC5D-directed CAR T Cell Therapy in Adult Participants with Relapsed or Refractory Multiple Myeloma (QUINTESSENTIAL)

1. Call to order:

The Meeting was called to order at 8:09 am Arizona 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 CC-95266, since it consists of primary human cells modified using 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 of CC-95266 locally**, provided that 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.

Points of Discussion:

1. An Institutional Representative confirmed that the biological safety cabinets (BSCs) were recently recertified and that the updated reports will be provided to IBC Services once they are available.
2. The Committee noted that the BSCs have been labeled with a biohazard symbol and an updated photo was provided as previously recommended.

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 8:15 am Arizona Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Amendment 02, dated 12-24-2024
Investigator's Brochure, Version 04, dated 10-01-2024
Global Product Administration Manual, Version 1.0, dated 09-27-2024
Research Modification Evaluation, Protocol, Amendment 01
Research Modification Evaluation, Protocol, Amendment 02
Research Modification Evaluation, Investigator's Brochure, Version 04
Research Modification Evaluation, Global Product Administration Manual, Version 1.0
Biological Risk Assessment and Summary, updated 01-15-2025
Research Modification Evaluation, PI Change, dated 06-12-2025
Site Map, BMDACC Infusion Suite, dated 05-12-2025
Site Map, BGMC 2nd Floor, dated 08-28-2023
Site Map, BMDACC 3rd Floor, dated 05-12-2025
Site Map, BGMC 5th Floor, dated 08-15-2023
Site Inspection Checklist, T Cell Studies, expires 03-06-2027, updated 06-12-2025
Photos, T Cell Studies, BMDACC and BGMC Dosing Rooms, dated 10-07-2024
Photos, T Cell and Non-T Cell, BMDACC Infusion Area, dated 08-28-2024
Photos, T Cell Studies, BMDACC, Cell Therapy Lab, dated 05-02-2025
Biohazard Sign, Genetically Modified Human Cells, dated 06-12-2025
Biological Safety Cabinet Certifications, Cell Therapy Lab, expires 06-2025
SOP, Biosafety for Genetically Modified Human Cells, dated 06-12-2025
SOP Addendum, Biosafety for Autologous Cells, dated 06-12-2025
Training, Shipping Certifications, expire 10-02-2025, 12-01-2025
CRRF, dated 03-13-2025
Prior Meeting Minutes, Initial, dated 06-10-2024
CV, Badari, A., signed 10-18-2024

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Tuesday, June 24, 2025**
Time:	8:00 am Arizona Time
Location:	Zoom Teleconference
Institution:	Banner Research, Gilbert, AZ
Principal Investigator:	**Hung T. Khong, MD**
Protocol:	Fate Therapeutics, Inc., **FT825-101**
NCT Number:	NCT06241456
Meeting Type:	Continuing Review of Protocol and Site
Title:	A phase 1 study of FT825/ONO-8250, an off-the-shelf CAR T-Cell therapy, with or without monoclonal antibodies, in HER2-Positive or other advanced solid tumors.

1. Call to order:

The Meeting was called to order at 8:15 am Arizona 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 FT825 since it consists of primary human cells modified by a plasmid and a CRISPR/Cpf1 ribonucleoprotein (RNP) complex. 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 FT825 locally**, provided that 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. The Committee had no questions or concerns about the facilities and practices.

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 Arizona Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Version 3.0, dated 05-27-2025
Investigator's Brochure, Version 2.0, dated 12-10-2024
Pharmacy Manual, Version 1.0, dated 08-29-2023
Research Modification Evaluation, Protocol, Version 3.0
Research Modification Evaluation, Protocol, Version 2.0
Research Modification Evaluation, Investigator's Brochure, Version 2.0
Biological Risk Assessment and Summary, updated 06-16-2025
Site Map, BMDACC Infusion Suite, dated 05-12-2025
Site Map, BGMC 2nd Floor, dated 08-28-2023
Site Map, BMDACC 3rd Floor, dated 05-12-2025
Site Map, BGMC 5th Floor, dated 08-15-2023
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, Biosafety for Genetically Modified Human Cells, dated 06-12-2025
SOP Addendum, Biosafety for Allogeneic Cells, dated 02-26-2025
Training, Shipping Certifications, expire 10-02-2025, 12-01-2025
CRRF, dated 03-03-2025
Prior Meeting Minutes, Initial, dated 06-10-2024