INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Tuesday, January 6, 2026**
Time:	10:00 am Eastern Time
Location:	Zoom Teleconference
Institution:	Inova Health Care Services, Fairfax, VA
Principal Investigator:	**Stephen Medlin, DO, FACP**
Protocol:	Kite Pharma, Inc., **KT-US-679-0788**
NCT Number:	NCT06413498
Meeting Type:	Initial 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 10:01 am Eastern 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 one local member unaffiliated with the institution. Also present were three 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 anitocabtagene autoleucel since it consists of primary human cells modified using a recombinant lentiviral vector.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of anitocabtagene autoleucel locally**, provided that all other criteria for study closure are 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 all biohazardous waste containers and other areas where the study agent is stored be labeled with a biohazard symbol.
2. An Institutional Representative confirmed that the internal transport containers are composed of corrugated plastic that can be easily decontaminated and are sealed using sturdy Velcro which lines the lip of the containers.
3. An Institutional Representative confirmed that there is an inner chamber inside the transport container where the study agent is placed and that there are insulated or frozen gel packs (depending on the temperature required for transport) surrounding the inner chamber. The Committee recommended that a photo of the inside of the transport container be provided to IBC Services.
4. An Institutional Representative confirmed that if used for transport, study agent infusion bags would be placed inside a biohazard bag lined with absorbent material and then placed in the inner chamber of the transport container.
5. An Institutional Representative confirmed that if the study agent is transported frozen to the subject's bedside for thawing, it will be transported inside the liquid nitrogen dewar.
6. An Institutional Representative confirmed that bedside preparation is preferred and will be used provided the Sponsor determines this to be acceptable. The Committee recommended that a Change in Research form be submitted to IBC Services if preparation occurs in a different location.
7. An Institutional Representative confirmed that the dosing rooms are not located in the [redacted]. The Committee recommended that site documents be revised to remove this reference from preparation and dosing room locations.
8. An Institutional Representative confirmed that the Biohazard Sign will be posted at the entrance to areas where the study agent is stored and handled.
9. An Institutional Representative confirmed that safety needles are used.
10. An Institutional Representative confirmed that prefilled disposable eyewash bottles are kept on a mobile cart and transported to the preparation/dosing rooms with the study agent.
11. An Institutional Representative confirmed that plumbed eyewash stations are checked weekly.

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 10:16 am Eastern Time.