

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Friday, October 31, 2025
Time: 10:30 am Eastern Time
Location: Zoom Teleconference
Institution: Orlando Health Cancer Institute, Orlando, FL
Principal Investigator: Tirrell T. Johnson, MD
Protocol: Binhui Biopharmaceutical Co., Ltd., BH-BS006-001
NCT Number: NCT05938296
Meeting Type: Continuing Review of Protocol and Site
Title: A Phase 1, Open-label Study of BS006, an Oncolytic Virus, Administered by Intratumoral Injection in Patients with Advanced/Metastatic Solid Tumors

1. Call to order:

The Meeting was called to order at 11:33 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 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 BS006, since it consists of a herpes simplex virus-2 vector administered by intratumoral injection. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **6 months after the last subject's last dose of BS006 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: 4 NO: 0 ABSTAIN: 0

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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 Section 3.3 be revised to replace the sentence about dilution of the study agent with, "In the event dilution is required, an appropriate volume of sterile saline is withdrawn directly into the syringe with the study agent using the same safety needle, after which the needle is recapped by engaging the safety mechanism and removed."
2. The Committee recommended that Biosafety SOP Section 3.4.1 be revised to remove "If the study agent is removed from its original sponsor packaging,".
3. The Committee discussed whether or not subjects are provided with instructions and supplies for disposal of dressings at home, including how to store them before returning them to the institution for disposal as biohazardous waste. An Institutional Representative stated that instructions and supplies are not currently provided to subjects.
4. The Committee recommended that the institution develop a plan for this and follow up with IBC Services on what subjects will be provided with. An Institutional Representative confirmed that they will reach out to the sponsor about obtain post-dosing educational materials for subjects and their caregivers and if these materials are not available will work with their Institution Review Board to create instructions. The Committee recommended that Biosafety SOP, Section 3.5 be revised accordingly after receipt of the follow-up information.
5. An Institutional Representative confirmed that the study agent-specific biohazard sign is posted at the entrance to the areas where the study agent is handled, including the storage, preparation, dosing rooms. The Committee recommended that the Photos document be updated with photos depicting doors and rooms properly labeled with biohazard signage.
6. An Institutional Representative confirmed that storage units used to store other genetically modified study agents are labeled with biohazard signage. The Committee recommended that updated photos be submitted to IBC Services.
7. The Committee recommended that a biohazard symbol be posted on the waterbath used to prepare study agents and that a photo be submitted to IBC Services.
8. The Committee recommended that a larger biohazard symbol be placed on the internal transport container and that a new photo of this container be submitted to IBC Services.
9. An Institutional Representative confirmed that pillows in the dosing area are made of a plastic (impervious) material, and that the covers are washable. The Committee recommended that Biosafety SOP Section 5 be revised to add a description of how bed linens would be handled in the event there was a leak of the study agent on bed linen.
10. The Committee recommended that Photos Slide 44 (Logs) be removed since this information is captured in other site-specific documentation.
11. The Committee recommended that the Institution confirm if study agent-specific biohazard signs are posted on the outside of biohazardous waste storage rooms when waste generated in this study is stored in the rooms.
12. The Committee discussed labeling biological safety cabinets (BSCs) with a biohazard sticker and noted that since this may not be required per state law, the biohazard signage on the door to the entrance of the preparation room is adequate.
13. An Institutional Representative confirmed that the yellow chemo hazardous containers arrive labelled with a biohazard symbol and that these containers are ultimately incinerated by the commercial biohazardous waste hauler. The Committee noted that these containers are acceptable for discarding biohazardous waste.
14. The Committee recommended that if the black hard-sided waste containers are used to dispose of biohazardous waste that these containers be appropriately labeled with a biohazard symbol.
15. An Institutional Representative confirmed that that storage room photos depict liquid nitrogen supply dewers and that nothing is stored in these dewers.

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16. An Institutional Representative confirmed that in [REDACTED], subjects may or may not be dosed with the study agent in bed. Some subjects may be sitting in a chair during dosing.
17. An Institutional Representative confirmed that biohazard waste containers will be available in all dosing rooms during dosing of the study agent.
18. An Institutional Representative confirmed that the [REDACTED] is no longer used. The Committee recommended that this location be removed from the Site Inspection Checklist.

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:

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|---|------------------------|
| 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 11:46 am Eastern Time.