

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Thursday, December 11, 2025
Time: 1:00 pm Eastern Time
Location: Zoom Teleconference
Institution: Norton Hospital, Louisville, KY
Principal Investigator: John T. Hamm, MD
Protocol: BioNTech SE, BNT113-01
NCT Number: NCT04534205
Meeting Type: Continuing Review of Protocol and Site
Title: An open label Phase II/III randomized trial of BNT113 in combination with pembrolizumab versus pembrolizumab monotherapy as a first line therapy in patients with unresectable recurrent, or metastatic Head and Neck Squamous Cell Carcinoma (HNSCC) which is positive for human papilloma virus 16 (HPV16+) and expresses PD-L1.

1. Call to order:

The Meeting was called to order at 1:28 pm Eastern 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 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: 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-1 containment facilities and practices plus Standard Precautions** are required for BNT113, since it consists of liposome-encapsulated mRNA molecules. 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 BNT113 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

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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 noted that the Biological Safety Cabinet Certification is expired and that an updated/current BSC Certification has been requested several times in the recent past.
2. The Committee **determined as a Condition of Approval** that the Institution must submit to IBC Services a current BSC Certification for the [REDACTED] BSC used to prepare the study agent, and this Certification must document that the BSC passed all required NSF49/ANSI tests.
3. The Committee noted that the Continuing Review Report Form indicates that a deviation or research-related incident occurred within the last year. The Committee recommended that the Institution confirm with IBC Services if the information in Section E of the CRRF is correct. If a deviation or research-related incident did occur, the Chair noted that IBC Services will follow-up with the Institution about this and will inform the Committee.
4. An Institutional Representative confirmed that the photo on the left in Slide 4 of the Photos document is of a laminar flow hood. The Committee recommended that the photo on the laminar flow hood be removed, since it is not used to prepare the study agent.
5. The Committee recommended that a new photo of the [REDACTED] as shown in Slide 6 of the Photos document be submitted to IBC Services.
6. The Committee noted that the photo of the prefilled disposable eyewash bottles shows that this bottle has expired. However, confirmation that prefilled disposable eyewash bottles are not expired are captured in other site-specific documents. The Committee recommended that a note be added to Slide 15 of Photos document stating that "expiration dates of prefilled disposable eyewash bottles are checked on a regular basis and this is a representative photo of prefilled disposable eyewash bottles", or a new photo (not showing an expiration date) of a representative prefilled disposable eyewash bottle be submitted to IBC Services.

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:

	APPROVED
X	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

For a vote of CONDITIONALLY APPROVED, the following condition must be met no later than January 11, 2026 in order to maintain IBC approval:

- a. A current Biological Safety Cabinet (BSC) Certification for the [REDACTED] BSC used to prepare the study agent must be submitted to IBC Services, and this Certification must document that the BSC passed all required NSF49/ANSI tests.

DETERMINATION VOTE - YES: 5 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 1:40 pm Eastern Time.

15. Post-meeting notes: The condition of approval was met on the following date: December 16, 2025

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Resolution of condition for Conditional Approval:

Condition No.	Resolution	Date of Resolution	Approved by Chair
a	A BSC Certification was submitted, and the BSC was certified according to NSF/ANSI 49 standards and passed all required tests	12-12-2025	12-16-2025