

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Wednesday, September 23, 2026
Time: 8:00 am Pacific Time
Location: Zoom Teleconference
Institution: Saint John's Cancer Institute, Santa Monica, CA
Principal Investigator: Naveed Wagle, MD
Protocol: [REDACTED] 1456-0001
NCT Number: NCT05155332
Meeting Type: Continuing Review of Protocol and Site
Title: Phase I open-label, dose escalation trial of BI 1831169 monotherapy and in combination with an anti-PD-1 antibody in patients with advanced or metastatic solid tumors.

1. Call to order:

The Meeting was called to order at 8:14 am Pacific 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 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: 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 noted 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 BI 1831169, since it is a replication-competent oncolytic virus derived from the VSV Indiana serotype. 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 BI 1831169 locally**, provided that all 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. An Institutional Representative confirmed that an automatic paper towel dispenser is located near the sink in the Procedure Room.

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 8:19 am Pacific Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 10.0, dated 03-10-2026

Protocol Clarification Letter, dated 03-30-2026

Investigator's Brochure, Version 8, dated 01-02-2026

Preparation and Administration Manual, Version 4.0, dated 05-15-2025

Pathogen Safety Data Sheet, Version 02, dated 08-09-2017

Research Modification Evaluation, Protocol, Version 10.0

Research Modification Evaluation, Protocol Clarification Letter, dated 03-30-2026

Research Modification Evaluation, Investigator's Brochure, Version 8

Biological Risk Assessment and Summary, updated 04-21-2026

Site Map, Cancer Center Clinic, Infusion Center, Basement, dated 02-25-2026

Site Map, Main Pharmacy, Vaccine Rm, BHW, Basement, dated 02-25-2026

Site Map, Saint John's Cancer Institute, 4th Floor Inpatient, dated 03-26-2026

Site Map, Saint John's Cancer Institute, Radiology, Endoscopy, dated 08-26-2025

Site Inspection Checklist, expires 07-20-2028

Photos, Biohazardous Waste, all protocols, dated 09-14-2026

Photos, Endoscopy, Radiology, 4th Floor Inpat Dosing Rm, dated 09-14-2026

Photos, Main Pharm, Vacc. Rm, Satellite Pharm, dated 09-14-2026

Photos, Procedure Rm, Cancer Ctr; Dosing Rm, Infusion Ctr, Basement, dated 09-14-2026

Biohazard Sign, BI 1831169, dated 08-25-2025

Biological Safety Cabinet Certification, expires 12-2026

SOP Biosafety for, BI 1831169, dated 10-03-2025

Training, Shipping Certification, expires 12-09-2027

CRRF, dated 06-24-2026

Prior Meeting Minutes, Continuing, dated 09-04-2025