Herbert Irving Comprehensive Cancer Center
Data and Safety Monitoring Committee (DSMC)

DSMC Safety Report Form

Section 1: Protocol Status		
IRB Number		
Protocol Title		
Reporting Interval		
Reporting Period: (MM/DD/YYYY – MM/DD/YYYY)		
Date of initial IRB approval:		
Does the study require CPDM to monitor?	☐ No	☐ Yes
Trial Type	☐ Single Center IST	☐ Multicenter IST List Affiliate Sites:
Section2: Enrollment Status		
Current Enrollment Status	☐ Open to Enrollment ☐ Pause/Hold Enrollment ☐ Closed to Enrollment	
# of Approved Accrual Target at all sites (per datasheet)		
Actual accrual to date (not including screen fails or withdrawals of consent)	___	# of patients enrolled at CUIMC: ___
# of Patients Active on Treatment	___	*** Sum of # of patients Active on Treatment, Long Term Follow Up, Off Study, withdrew or removed from study treatment must equal # of Actual accrual to date*
# of patients in Long-term Follow Up	___	
# of patients Off Study	___	
# of patients who withdrew or removed from study treatment for any other reason.	___	

Version date: 04-08-2024

Section 3 **Patient Status Reasons**		
# of patients considered unevaluable		List of patients ID:
# of patients **who** discontinued study treatment due to unacceptable toxicity		List of patients ID:
# of patients **who** withdrew consent from study treatment / procedures		List of patients ID:
# of patients **who** were removed from study treatment per Investigator discretion		List of patients ID:

Section 4: **Protocol Major Violations and Unanticipated Problems**		
Did any Major Violations and/or Unanticipated Problems occur throughout the life of this study?		☐ Yes (please complete details below) ☐ No Major Violations or Unanticipated Problems have been reported throughout the life of this study
Major Violation / UP (include Site and Patient Study ID)	**Date**	**Protocol Amendment Initiated? (Yes/No)**

Section 5: **Serious Adverse Events and Dose Limiting Toxicities**				
Did any patients experience a SAE or DLT during this reporting period?		☐ Yes (please complete details below) ☐ No SAEs or DLTs reported during this period		
Patient Study ID	**CTCAE Term & Grade**	**Start Date - End Date**	**Related to Study Drug? (Yes/No, if multiple, specify for each drug)**	**Is the event a DLT? (Yes/No)**

Section 6: **Adverse Events**			
Did any patients experience an adverse event ≥ grade 3?		☐ Yes (details below) ☐ No	
List Study-wide Toxicities by keyword	**Grade (≥3 events)**	**Number of CUIMC Patients**	**Number of Patients Experiencing this Toxicity, Study-wide**

***Please **bold** new adverse events ≥ grade 3 that occurred during this reporting period.

Section 7 **Phase I Therapeutic Trials**		
☐ Not Applicable		
Has the dose escalation schema in the protocol been followed?		☐ Yes ☐ No
Which cohort is currently accruing patients?		
Has the Maximum Tolerated Dose (MTD) Been Reached?		☐ Yes, MTD: _____ ☐ No
Total # of Dose Limiting Toxicities (List DLTs below)		
DLT Term	**Study ID**	**Patient Cohort**

Section 8 **Phase II Therapeutic Trials**	
☐ **Not Applicable**	
Has this trial demonstrated efficacy?	☐ Yes ☐ No ☐ Insufficient Data at this time

Section 9: **Analyses and Publication**	
Has the primary objective been met?	☐ Yes Date: _____ Primary Objective per Protocol: ☐ No
Has an interim analysis been completed for this study?	☐ Yes (See Attached) ☐ No
Has an abstract, manuscript, or poster been drafted/published for this study?	☐ Yes (See Attached) ☐ No

Section 10: **Closure**		
If this protocol employs an early stopping rule, please define it. (Copy and paste from protocol)		
Are there any plans to close the study in the near future?	☐ No	☐ Yes (Specify why) _____
Is this the last safety report to be submitted to the DSMC?	☐ No	☐ Yes

PI SIGNATURE: _____

Date: _____