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|  | Department of Health & Human Services PROTOCOL STATUS UPDATE v3.2 | Public Health Service  National Institutes of Health  National Cancer Institute  Bethesda, Maryland 20892 |

The Cancer Therapy Evaluation Program (CTEP), National Cancer Institute, as a sponsor of clinical trials, reviews the status of each clinical trial on an ongoing basis. To help us update our records, prioritize resources, and evaluate development plans for each agent, please complete the form below to update CTEP on the status and status date of your study. **Please e-mail this form to the Protocol and Information Office at** [**PIO@CTEP.NCI.NIH.gov**](mailto:PIO@CTEP.NCI.NIH.gov)**.**

Protocol Title:

NCI Protocol #: Local #: IND #:

Principal Investigator:

*Select each applicable change and provide the corresponding date:*

Change in Anticipated Primary Completion Date Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Definition: the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the prespecified protocol or was terminated.*

ACTIVE Date:

*Definition: Trial is open to accrual.*

TEMPORARILY CLOSED TO ACCRUAL Date:

*Definition: Trial is temporarily not accruing.*

Reason (required): Please select only one reason.

Accrual target was reached for this phase of the study

Adverse Event Assessment

CTEP Initiated Action

Closed Prematurely

FDA Regulated Intervention

Lack of Drug Supply

Lack of Funding

Slow Accrual

TEMPORARILY CLOSED TO ACCRUAL AND TREATMENT Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Definition: Trial is temporarily not accruing and patients are not receiving therapy.*

Reason (required): Please select only one reason.

Accrual target was reached for this phase of the study

Adverse Event Assessment

CTEP Initiated Action

Closed Prematurely

FDA Regulated Intervention

Lack of Drug Supply

Lack of Funding

Slow Accrual

CLOSED TO ACCRUAL, PATIENTS STILL ON TREATMENT Date:

*Definition: The protocol has been closed to patient accrual. Patients are still receiving therapy.*

CLOSED TO ACCRUAL, ALL PATIENTS HAVE COMPLETED TREATMENT Date:

*Definition: The protocol has been closed to patient accrual. All patients have completed therapy, but patients are still being followed according to the primary objectives of the study. No additional investigational agents are needed for this study.*

COMPLETED Date:

*Definition: The protocol has been closed to accrual, all patients have completed therapy, and the study has met its primary objectives. A final study report/publication has been submitted to CTEP.*

Publication Citation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ or  Publication in Press \_\_\_\_\_\_\_\_\_\_\_\_\_\_

ADMINISTRATIVELY COMPLETED Date:

*Definition: The protocol has been completed prematurely (e.g., due to poor accrual, insufficient drug supply, IND closure). The trial is closed to further accrual and all patients have completed protocol treatment. A final study report is not anticipated.*

Reason (required): Please select only one reason.

Accrual target was reached for this phase of the study

Adverse Event Assessment

CTEP Initiated Action

Closed Prematurely

FDA Regulated Intervention

Lack of Drug Supply

Lack of Funding

Slow Accrual

NAME of person completing this form: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**\_\_\_\_**