

North Central Cancer Treatment Group

N0177: A Pilot and Phase II Study of OSI-774 and Temozolomide in Combination with Radiation Therapy in Glioblastoma Multiforme

Addendum 9 – July 8, 2005

Summary

This amendment is in response to the revised Adverse Event Reporting Requirements that were distributed by CTEP in a communication from Mike Montello, PharmD. in January 2005.

- Change in the reporting timeframes for AdEERS reports: The timeframe for submitting a fully detailed AdEERS report for events which require AdEERS notification within 24 hours has changed from seven (7) working days to three (3) calendar days. The timeframe for other events requiring AdEERS reporting has been changed from seven (7) working days to seven (7) calendar days.
- Clarification of the requirement for an AdEERS report for certain serious events that occur >30 days following agent administration: A fully detailed AdEERS report is to be submitted for grade 3 (with hospitalization/prolongation of hospitalization) or grade 4 when the event occurs more than 30 days after receiving an agent under a CTEP IND. For a complete discussion and breakdown of the revised requirements, refer to the “CTEP, NCI Guidelines: Adverse Event Reporting Requirements (December 15, 2004 version)” which is accessible from the CTEP home page at <http://ctep.cancer.gov>.

Replacement pages are provided. Please incorporate into the protocol and keep this addendum with your protocol

Title page: Now reflects Addendum 9 and revised NCI version date.

Page 28: The second sentence of Section 10.1 (Adverse Event [AE] Reporting and Monitoring) has been revised to reflect the correct CTEP web site to access the CTC as follows:

The CTC version 2.0 can be downloaded accessed from the CTEP home page (<http://ctep.info.nih.gov/reporting/etc.html> <http://ctep.cancer.gov>).

Page 28: The first and second paragraphs of Section 10.11 (Adverse Event [AE] Reporting and Monitoring) have been revised to reflect the current CTEP mandated adverse event reporting guidelines as follows:

Adverse event monitoring and reporting is a routine part of every clinical trial. First, identify and grade the severity of the event using the CTC. Next, determine whether the event is expected or unexpected (~~refer to see~~ Section ~~15.0~~ **10.12**) and if the adverse event is related to the medical treatment or procedure (see Section ~~10.12~~ **10.13**). With this information, determine whether ~~an adverse event~~ **the event should must** be reported as an expedited report (see Section 10.2) ~~or as part of the routinely reported clinical data~~. **All AEs reported via expedited mechanisms must also be reported via the routine data reporting mechanisms defined by the protocol (see Sections 10.3 and 18.0).**

Expedited adverse event reporting requires submission of an ~~electronic~~ Adverse Event Expedited Reporting System (AdeERS) report(s). ~~Twenty-four (24) hour electronic notification of NCI may also be required~~ **Other expedited reporting requirements and systems may also apply**. ~~Twenty-four (24) hour notification and AdeERS reports~~ **Expedited and routine reports** are to be completed within the timeframes specified in Sections 10.2 **and 10.3**. All expedited ~~adverse event~~ **AE reports should must** also be submitted to the local Institutional Review Board (IRB) **according to local IRB's policies and procedures**.

Pages 28-29: New Section 10.12 (Expected vs. Unexpected Events) has been added to reflect the current CTEP mandated adverse event reporting guidelines and remaining sections have been renumbered.

Page 29: Previous Section 10.12 has now become Section 10.13.

Section 10.14 (Additional instructions...) is newly added to reflect the current CTEP mandated adverse event reporting guidelines.

Pages 30-32: Section 10.2 (Expedited Reporting Requirements) has been replaced in its entirety to reflect the current CTEP mandated adverse event reporting guidelines.

Pages 30-37: Repagination only.