

North Central Cancer Treatment Group

N0779: Phase II Study of Vorinostat (SAHA) in Combination with Bortezomib (PS-341) in Patients with Recurrent Glioblastoma Multiforme

Addendum 1 – November 21, 2008

Summary

- Administrative/editorial changes.

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

Title page Updated to reflect the addition of Addendum 1 and revised NCI version date.

Protocol Resource Page

Page 2: The title for Janis Wobschall has been updated as follows:
NCCTG *Research Base* **Research Protocol Development Coordinator Specialist**

The title for Christine R. Maszk has been updated as follows:
NCCTG *Research Base* **Research Pathology Coordinator**

Section 4.0 **Test Schedule**

Page 18: footnote #5 has been corrected as follows:
Patients undergoing surgery will have a post procedure MRI performed ≤ 7 days after surgery and ≤ 218 days prior to initiation of post surgery treatment.

Section 17.0 **Pathology Considerations/Tissue Biospecimens**

Page 52: A new bullet has been added to Section 17.22 as follows to reflect current template language:

17.22 The following materials below are mandatory (unless indicated otherwise) and required for shipment:

- Diagnostic slides from all surgical biopsies
- Pathology Reporting Form
- **Pathology Submission Form**
- Surgical Pathology Report
- Operative Report (*optional*)

Page 53: The address in Section 17.262 has been updated as follows to reflect current template language:

NCCTG Operations Office
Attn: NCCTG PC Office (**Study N0779**)
RO_FF_03_24-CC/NW Clinic
200 First Street SW
Rochester, MN 55905

Page 54: The second and last sentences have been bolded as follows:
Submit one formalin fixed paraffin-embedded (FFPE) tumor tissue block with representative tumor from each surgical biopsy. **A corresponding H & E slide for each block must be submitted** to permit quality assessment of each tissue block. Material obtained at the time of initial diagnosis of glioblastoma multiforme should be submitted in addition to material obtained at recurrence (NOTE: gliosarcomas and other grade 4 astrocytoma variants [e.g., giant cell]) may be submitted. The FFPE tissue block is preferred; however, **if an institution is unable to provide a tissue block, slides may be submitted (see Section 17.311 and 17.312).**

A portion of the heading in Section 17.311 has been bolded as follows:
Patients Not Undergoing Surgery (**Arm A**)

A portion of the heading in Section 17.312 has been bolded as follows:
Patient Undergoing Surgery at Time of Recurrence (**Arm B**)

Page 55: The first bullet in Section 17.32 has been corrected as follows:

- Paraffin Embedded Tissue Block(s) with corresponding H&E slide(s) ~~or~~ **OR** Unstained/Slides with corresponding H&E slides)

The address in Section 17.36 has been updated as follows to reflect current template language:

NCCTG Operations Office
Attn: NCCTG PC Office (**Study N0779**)
RO_FF_03_24-CC/NW Clinic
200 First Street SW
Rochester, MN 55905

Page 57: The first sentence of the second paragraph in Section 17.6 has been corrected as follows:
...IRB review and approval will be sought regarding the most appropriate manner of disclosure **and** whether or not validation...

Appendix IB

Page 2:

Consent Form

A new third sentence has been added to the first paragraph in the section “After surgery” for further clarification as follows:

Vorinostat and bortezomib therapy will not restart until you are recovered from any side effects of surgery. The maximum recovered time allowed is 4 weeks. **Within 7 days after surgery, you will have an MRI with contrast done for tumor measurement and another MRI with contrast within 28 days of starting treatment.**