

North Central Cancer Treatment Group

N0626: Phase II Randomized Study Pemetrexed With Sorafenib versus Pemetrexed Alone as Second-line Therapy in Patients With Advanced Non-Small Cell Lung Cancer

Addendum 1 – November 30, 2007

**Summary**

- Clarifications have been made throughout the protocol.
- Administrative/editorial changes.

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

**Title page** Updated to reflect Addendum 1 and revised NCI version date.

**Protocol Resources**

Page 2: The NCCTG Research Base Pathology Coordinator order has been revised. Christine Maszk is now listed as the first contact and Helen Tollefson is the second contact. Under the “Questions” column, “~~Pathology~~” has been changed to “**Paraffin-embedded tissue pathology.**”

**Jacqueline M. Lafky** has been added as “Non-paraffin Biospecimens” resource person.

**Index Page**

Page 3: The title for Section 14.0 has been revised to read “~~Non-solid Tissue (Body Fluid)~~ Biospecimens.”

**Section 3.0** **Patient Eligibility**

Page 16: Section 3.19d has been revised for clarification as follows:  
Previously treated with  $\geq 1$  chemotherapy regimen. ~~NOTE: This does include adjuvant treatment.~~ **Prior treatment with adjuvant chemotherapy is allowed and not counted as a regimen.**

Page 18: The first sentence of Section 3.29b has been revised for clarification as follows:  
...was diagnosed and definitively treated  $\leq \geq 5$  years previously with no subsequent evidence of recurrence.

**Section 4.0**

Page 20:

**Test Schedule**

The first sentence of footnote #6 has been revised for clarification as follows:

Three 10 mL samples in EDTA tubes **of whole blood** and one 10 mL sample in sodium heparin tubes (**processed into plasma and red blood cells at the participating sites**) drawn prior to treatment and 24 hours post-treatment of cycle 1 – mandatory.

**Section 14.0**

Page 39:

**Non-solid Tissue (Body Fluid) Biospecimens**

The title of Section 14.0 has been revised as follows:

~~Non-solid Tissue (Body Fluid) Biospecimens~~

**Section 17.0**

Page 62:

**Pathology Considerations/Tissue Biospecimens**

Tissue specimen submissions are mandatory for eligibility. Therefore, the “NOTE” in Section 17.1 does not apply and has been deleted as follows:

~~NOTE: If an institution is not able to provide the tissue sample(s), it does not cause the patient to be ineligible. Patients must have consented to submission of the FFPE tissue(s).~~

**Section 18.0**

Page 65:

**Records and Data Collection Procedures**

The following clarifications have been made to this section:

- Reference to footnote #8 for the “Hematology Interval Laboratory Form” has been revised to reflect reference to footnote #6.
- The X under the “At each evaluation” column for “Evaluation/Observation form” has been deleted.
- Reference to new footnote #7 has been placed after “ADR/AER (See Section 10.0)”<sup>7</sup>
- Footnote #7 is newly added “**If a female patient or a male patient’s spouse becomes pregnant during the study, please complete the Bayer Pregnancy Form found in the Forms Packet and e-mail within 3 working days to: [wh-adverse.events@bayer.com](mailto:wh-adverse.events@bayer.com).**”

**Appendix I**

Page 10:

**Consent Form**

The second sentence of the first paragraph under the “Rare but serious” section for pemetrexed has been revised as follows:

Aspirin and aspirin-like drugs can cause trouble with your ~~choice~~ **ability** of passing pemetrexed through your body...

**Appendix V**

Page 1:

**Summary Table of Research Blood/Blood Products Being Received in BAP for N0626**

Reference to a specific tracking system is being removed. Therefore, footnote #1 has been revised as follows:

Record receipt of specimens ~~in the Research Accessioning Tracking System (RATS).~~