

North Central Cancer Treatment Group

N0321: Phase I/II Study of PS-341 in Combination with Paclitaxel, Carboplatin, and Concurrent Thoracic Radiation Therapy for Non-small Cell Lung Cancer (NSCLC)

Addendum 9 – June 13, 2008

**Summary**

- An additional dose level has been added to the Phase I Component. As a result, the schema and Section 7.0 have been updated accordingly.
- Appendices IA and IB have been updated with an additional risk for consistency with Section 15.0 of the protocol.
- Editorial/administrative changes.

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

**Title Page**

The phone number for Dr. Adjei has been updated as follows:  
507/266-0268 **538-5843**

Updated to reflect Addendum 9 and revised NCI version date.

**Protocol Resources**

Page 2: **Sarah Hanson** replaces ~~Paula Stellmaker~~ as NCCTG *Research Base* Quality Control Specialist.

Helen Tollefson has been removed as NCCTG *Research Base* Pathology Coordinator.

The fax number for Jacqueline M. Lafky has been updated as follows:  
(507) ~~284-8105~~ **266-0824**

**Schema**

Page 4: The first paragraph on the Phase I Schema has been revised as follows:  
Prior to discussing protocol entry with the patient, call the ~~Randomization Center~~ **Registration Office** to ensure that a place on the protocol is open to the patient. If an opening is available, a slot may be reserved for no longer than 5 working days.

Page 4: Due to an additional dose level being added to the Phase I Component, the dose level table has been revised as follows:

Dose level	PS-341 mg/m <sup>2</sup>	Paclitaxel mg/m <sup>2</sup>	CBDCA AUC
-1	0.5	120	5
0	0.5	135	5
**1	0.5	150	5
2	0.8	150	5
3	1.0	150	5
4	1.0	175	5
5	1.0	175	6
<b>6</b>	<b>1.2</b>	<b>175</b>	<b>6</b>

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

Page 12:

The first paragraph of Section 3.0 has been revised as follows:

Phase I Component Only: Prior to discussing protocol entry with the patient, call the ~~Randomization Center~~ **Registration Office** to ensure that a place on the protocol is open to the patient. If an opening is available, a slot may be reserved for no longer than 5 working days.

### **Section 6.0** **Registration/Randomization Procedures**

Pages 14-16:

The first paragraph of Section 6.1, Sections 6.11, 6.12, and 6.21 have been revised as follows:

Prior to discussing protocol entry with the patient, call the ~~Randomization Center~~ **Registration Office** to ensure that a place on the protocol is open to the patient. If an opening is available, a slot may be reserved for no longer than 5 working days.

- 6.11 To register a patient, call (507/284-4130) or fax (507/284-0885) a completed eligibility checklist to the ~~Randomization Center~~ **Registration Office** between 8 a.m. and 4:30 p.m. central time Monday through Friday.
- 6.12 ~~Randomization Center~~ **Registration Office** will register patients separately to the optional translational research component of this study (see Section 14.0).
- 6.21 To register a patient, access the NCCTG web page at <https://ncctg.mayo.edu/training> and enter the remote registration/randomization application. The remote registration/randomization application is available 24 hours a day, 7 days a week. Back up and/or system support contact information is available on the Web site. If unable to access the Web site, call the NCCTG ~~Registration/Randomization Center~~ **Office** at (507)-284-4130 between the hours of 8 a.m. and 4:30 p.m. Central Time (Monday through Friday).

**Section 7.0**    **Protocol Treatment**

Page 18:    The second column of the table in Section 7.12 has been revised as follows:

As assigned by NCCTG ~~Random Center~~ **Registration Office**

Page 19:    Due to an additional dose level being added to the Phase I component of this study, the table in Section 7.13 has been revised as follows:

Dose level	PS-341 mg/m <sup>2</sup>	Paclitaxel mg/m <sup>2</sup>	CBDCA AUC
-1	0.5	120	5
0	0.5	135	5
*1	0.5	150	5
2	0.8	150	5
3	1.0	150	5
4	1.0	175	5
5	1.0	175	6
<b>6</b>	<b>1.2</b>	<b>175</b>	<b>6</b>

**Section 12.0**    **Descriptive Factors**

Page 36:    Due to an additional dose level being added to the Phase I component of this study, a new descriptive factor has been added as follows:

**12.6    Dose level (assigned by Registration Office): -1 vs. 0 vs. 1 vs. 2 vs. 3 vs. 4 vs. 5 vs. 6.**

**Section 14.0**    **Translational/Pharmacologic Studies (Optional):**

Page 38:    The second to the last paragraph in Section 14.3 has been revised for clarification as follows:

The blocks/slides will be forwarded by the NCCTG ~~Research~~ **Pathology** Coordinator to the TACMA Biospecimen Laboratory, Stable 13-10, Mayo Clinic Rochester, **for immunohistochemistry staining.**

**Appendices IA and 1B Consent Forms**

Page 7:    In order to be consistent with the Drug Information section (Section 15.0) of the protocol, **weight gain** has been added to the “Less Likely” category for PS-341.