

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 10 – August 29, 2008

Summary

- The Drug Information and consent form have been updated based on the receipt of an updated package insert for Carboplatin dated January 2004.
- Editorial/administrative changes.

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

Title Page

Updated to reflect Addendum 10 and revised NCI version date.

Protocol Resources

Page 2: **Susan Haithcox, OCN, CCRP** replaces ~~Wanda DeKrey, R.N.~~ as the NCCTG Member Nurse.

The title for Alicia Elsing has been updated as follows:

NCCTG *Research Base* ~~Protocol Development Coordinator~~ **Research Protocol Specialist**

Jennifer S. Mentlick replaces ~~Christine R. Maszk~~ as the NCCTG *Research Base* Pathology Coordinator.

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

Page 38: For clarification purposes, the last paragraph of Section 14.3 has been revised as follows:

The institutional pathologist must be notified that a block may be depleted. Remaining material will be stored by NCCTG for future research, **according to patient consent (see Section 6.14)**, although the blocks will be promptly returned to the institutional pathologist upon request at any time.

Section 15.0 **Drug Information**

Page 45: Due to the receipt of the updated package insert for Carboplatin and to bring this section up-to-date with the current template guidelines, Section 15.32 has been updated as follows:

15.32 Known potential toxicities: Myelosuppression, nausea, vomiting, and electrolyte loss are most common. **Hypocalcemia, hypokalemia, hypomagnesemia, and hyponatremia may occur, although these are rarely associated with symptoms.** Peripheral neuropathies, **diarrhea, constipation, mucositis, hypotension, hypertension, visual disturbances, ototoxicity, changes in taste,**

CNS symptoms, rare bronchospasms, abnormal kidney and liver tests, pain, alopecia, fever, change in appetite and weight, and secondary leukemia and/or myelodysplastic syndrome are less common ~~may also occur~~. Dermatologic reactions have also been reported. **Allergic reactions with congestion, nausea, vomiting, rash, chills, tingling of the extremities, dyspnea, or anaphylactic-like symptoms can rarely develop after repeated treatments.**

Appendices IA and 1B Consent Forms

Page 5: Due to the receipt of the updated package insert for Carboplatin, the following revisions have been made to the risk section of the consent forms:

~~More common~~ **Likely** side effects:

- ~~Loss of~~ **Change in appetite or weight** (*wording expanded*)
- Nausea (feeling sick to the stomach)
- Vomiting (throwing up)
- ~~Trouble passing stool~~ (*moved to Less likely and reworded*)
- ~~Mouth sores~~ (*moved to Less likely*)
- ~~Hearing trouble~~ (*moved to Less likely and reworded*)
- ~~Fall in white and red blood cell and platelet counts which may raise the risk of infection, anemia, bruising, and bleeding~~ (*as shown below, split into 3 separate entries and reworded*)
- **Low white blood cell counts leading to an increased risk of infections with or without fever**
- **Low platelet count leading to an increased risk of bleeding**
- **Low red blood cell count causing anemia**
- ~~Tingling of the hands and feet~~ (*duplicate entry*)
- ~~Hair loss~~ (*moved to Less likely and wording expanded*)
- ~~Loose stools~~ (*moved to Less likely and wording expanded*)
- ~~Abnormal kidney and liver tests~~ (*moved to Less likely and split into 2 separate entries*)
- ~~Low blood pressure~~ (*moved to Less likely and wording expanded*)
- ~~Change in taste~~ (*moved to Less likely*)
- Abnormal mineral levels in the blood
- ~~Trouble with eyesight~~ (*moved to Less likely and reworded*)
- ~~Tingling or numbness in the fingers or toes~~ (*moved to Less likely and wording expanded*)
- ~~Allergic reactions (rash, hives, redness, itching, and trouble breathing (with wheezing), and skin rash~~ (*moved to Less likely*)
- **Change in blood tests, particularly loss of magnesium** (*newly added*)

Less likely side effects:

- **Difficult bowel movements (constipation)** (*moved from Likely and reworded*)
- ~~Mouth sores~~ (*moved from Likely*)
- ~~Change in taste~~ (*moved from Likely*)
- ~~Hearing problems~~ (*moved from Likely and reworded*)
- **Fever** (*newly added*)
- **Numbness and/or tingling of the hands and feet, usually this goes away after the drug is stopped, however for some patients this may not ever go away** (*moved from Likely and wording expanded*)
- ~~Hair loss or thinning~~ (*moved from Likely and wording expanded*)

- **Loose stools (diarrhea)** (*moved from Likely and wording expanded*)
- **Abnormal kidney tests** (*moved from Likely*)
- **Abnormal liver tests** (*moved from Likely*)
- **Low or high blood pressure** (*moved from Likely and expanded to include “high”*)
- **Vision problems** (*moved from Likely and reworded*)
- **Allergic reactions (rash, hives, redness, itching, swelling, and difficulty in breathing with wheezing), and skin rash** (*moved from Likely – swelling newly added*)
- **Other skin rashes** (*newly added*)

~~Less common~~ **Rare but serious** side effects:

- Secondary leukemia and/or myelodysplastic syndrome (damage to the bone marrow that affects the making of normal blood cells)