

North Central Cancer Treatment Group

N064B, Randomized Phase II Trial of Panitumumab, Erlotinib, and Gemcitabine vs. Erlotinib and Gemcitabine in Patients with Untreated, Metastatic Pancreatic Adenocarcinoma

Addendum 9 – March 11, 2011

**Summary**

- Contact information for RPS III has been updated
- Contact information for the Data Management Specialist has been removed.
- Based on review of the panitumumab investigator brochure 9.1 dated August 19, 2010 revisions have been made to Section 15.0 and the consent form
- Administrative/editorial changes.

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

**Title page** Revised NCI version date and Addendum 9 have been added.

**Protocol Resources**

Page 2: Contact information has been revised for the Research Protocol Specialist III, as follows:

~~Linda S Long~~ **Sanna McKinzie**  
NCCTG Research Base Research Protocol Specialist III  
Phone: 507-266-3853 **538-6646**  
Fax: 507-284-5280  
E-mail: [long.linda@mayo.edu](mailto:long.linda@mayo.edu) [mckinzie.sanna@mayo.edu](mailto:mckinzie.sanna@mayo.edu)

The Research Base Data Management Specialist contact has been removed (Linda Berge). Please contact the NCCTG Research Base Quality Assurance Specialist (QAS) for technical questions regarding electronic form entry.

**Section 10.0 Adverse Event (AE) Reporting and Monitoring**

Page 42: The last bullet point in Section 10.21 has been revised with current information, as follows:

- In the rare event when Internet connectivity is disrupted, a **24-hour notification is to be made to NCI by telephone at: 301-897-7497. An electronic report MUST be submitted immediately upon re-establishment of internet connection. Please note that all paper AdEERS forms have been removed from the CTEP website and will NO LONGER be accepted.** ~~a report may be prepared using the Adverse Event Expedited Report—Single Agent or Multiple Agents paper template (available on the CTEP Home Page at <http://ctep.cancer.gov>). Contact the NCCTG SAE Coordinator (as identified on the NCCTG Protocol Resources page) for back-up submission instructions.~~

The first row of the table in Section 10.22 has been revised for correction, as follows:

EVENT TYPE	REPORTING PROCEDURE
Secondary AML/MDS	<p>Reporting for this event required during and after completion of study treatment, via AdEERS.</p> <p><del>Through December 31, 2010, continue using CTCAE v3.0: Report Myelodysplasia as “Blood/Bone Marrow – Myelodysplasia” and Leukemias as “Blood/Bone Marrow – Other (Specify, ___)”.</del></p> <p>Beginning January 1, 2011, AdEERS will only accept CTCAE v4.0 for this study: Report these events using “Neoplasms benign, malignant and unspecified (including cysts and polyps)” <i>Other (Specify, ___)</i>” <b>and including the appropriate adverse event:</b></p> <ul style="list-style-type: none"> <li>- <b>Leukemia secondary to oncology chemotherapy</b></li> <li><b>OR</b></li> <li>- <b>Myelodysplastic syndrome</b></li> <li><b>OR</b></li> <li>- <b>Treatment related secondary malignancy.</b></li> </ul>

**Section 15.0 Drug Information**

Page 71:

Based on review of the panitumumab investigator brochure 9.1 dated August 19, 2010 revisions have been made to Section 15.344, as follows:

- Allergy/Immunology: Allergic reaction, **in rare circumstances can include the development of antibodies directly against panitumumab, potentially rendering it less effective.**
- Cardiac: Acute myocardial infarction, myocardial infarction, cardio-respiratory arrest, cardiac arrest,
- Constitutional symptoms: Fever, fatigue
- Dermatology/skin: Dermatitis acneiform, pruritus, erythema, rash, skin exfoliation, paronychia, dry skin, skin fissures, nail changes, excessive growth of eyelashes, macular-papular rash, **wound dehiscence.** Infectious complications including sepsis, in rare cases leading to death, and abscesses requiring incisions and drainage were reported.
- Gastrointestinal: Stomatitis, mucositis, diarrhea, dehydration, nausea, vomiting, dry mouth, lips, or nose, **intestinal perforation.**
- Hemorrhage/bleeding: Nose bleeds...

**Appendix I** **Consent Form**

Pages 11/12: Based on review of the panitumumab investigator brochure 9.1 dated August 19, 2010 revisions have been made to the “Rare but serious risks of panitumumab” and a paragraph located after this section. Changes are as follows:

Rare but serious risks of panitumumab (events occurring less than 2-3% of the time)

- Collection of fluid in the space around the lung (pleural effusion)
- Fever, chills, swelling of body, shortness of breath (allergic reaction)
- Inflammation/infection of the lungs (pneumonitis)
- Scarring of the lungs (pulmonary fibrosis)
- Swelling in the body, especially in the arms and legs (edema)
- Blood clots in the lungs which could be life threatening or cause death (pulmonary embolism)
- Blood clot in vein (deep vein thrombosis)
- Inflammation of veins (phlebitis)
- High blood pressure (hypertension)
- Lack of oxygen to the heart muscle which can cause damage to the heart (heart attack)
- Heart stops beating, which can cause death (cardiac arrest)
- Breathing stops, which can cause death (respiratory arrest)
- Lack of oxygen to the brain caused by either bleeding in the brain or blood clot. Also called a stroke (cerebrovascular accident)
- **Infection that has spread to the bloodstream and can cause low blood pressure, fever, and/or death (sepsis)**
- **Development of a hole or tear in the intestine, which can cause damaging intestinal fluids to leak into the abdominal cavity, resulting in bleeding, severe pain, fever, nausea, vomiting, infection and possibly death (intestinal perforation)**
- **Breakdown of a wound that has already healed (wound dehiscence)**

The risks of panitumumab used in pancreatic cancer with other agents is unknown.

As with any medication, allergic reactions are a possibility. **In rare circumstances the reaction can include the development of antibodies (special kinds of proteins produced by the immune system designed to recognize and stop foreign substances in the body) directly against panitumumab, potentially rendering it less effective.**