

North Central Cancer Treatment Group

N064A, Phase II Study of Panitumumab, Chemotherapy, and External Beam Radiation in Patients with
Locally Advanced Pancreatic Cancer

Addendum 7 – March 18, 2011

Summary

- 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 with your protocol.

Title Page The Addendum 7 has been added and the NCI version date has been updated.

Section 15.0
Page 66

Drug Information

Based on review of the Panitumumab investigator brochure 9.1 dated August 19, 2010 revisions have been made to Section 15.144, 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

Pages 12/13

Consent Form

Based on review of the Panitumumab investigator brochure 9.1 dated August 19, 2010, three risks have been added at the end of the “Rare but serious risks of Panitumumab” and a paragraph has been added after this section, as follows:

- **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 are 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.