

NORTH CENTRAL CANCER TREATMENT GROUP
Eligibility Checklist

4/2/2010
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N064B: Randomized Phase II Trial of Panitumumab, Erlotinib, and Gemcitabine vs. Erlotinib and Gemcitabine
in Patients with Untreated, Metastatic Pancreatic Adenocarcinoma

For the first 6-12 patients enrolled on study: Prior to discussing protocol entry with the patient, call the Registration Office (507/284-4130) to insure that a place on the protocol is open to the patient.

First 6-12 patients: To register a patient, call (507/284-4130) or fax (507/284-0885) a completed eligibility checklist to the Registration Office between 8 a.m. and 4:30 p.m. central time Monday through Friday.

Following first 6-12 patients: To register a patient, access the NCCTG web page at <https://ncctg.mayo.edu/training> and enter the remote registration/randomization application.

Registration date (date on) (mm/dd/yyyy) ___/___/_____

Patient study ID number (provided at time of Reg/Random) _____

NCCTG member (participant sponsor) _____

NCCTG treating location _____

NCCTG treating physician _____

Institution patient number (local subject number) _____

IRB approval date (mm/dd/yyyy) ___/___/_____

Person Completing Form:

Last Name: **(print)** _____ First Name: **(print)** _____

Phone: _____ Fax: _____ Email: _____

Patient initials (last, first, middle) _____

Gender (check one) ___ Male ___ Female ___ Unknown

Date of birth (mm/dd/yyyy) ___/___/_____

ZIP code _____

Country of Residence _____

Race (check all that apply)

- ___ White
- ___ Black or African American
- ___ Native Hawaiian or Other Pacific Islander
- ___ Asian
- ___ American Indian or Alaska Native
- ___ Not reported: Patient refused or not available
- ___ Unknown: Patient unsure

Method of payment (check one)

- ___ PI (Private Insurance)
- ___ MR (Medicare)
- ___ MRP (Medicare and Private Insurance)
- ___ MD (Medicaid)
- ___ MM (Medicaid and Medicare)
- ___ MVA (Military or Veterans Sponsored,
Not Otherwise Specified (NOS))
- ___ MS (Military Sponsored [including CHAMPUS & TRCARE])
- ___ MV (Veterans Sponsored)
- ___ SP (Self pay [no insurance])
- ___ NP (No means of payment [no insurance])
- ___ OTH (Other)
- ___ UNK (Unknown)

Ethnicity (check one)

- ___ Not Hispanic or Latino
- ___ Hispanic or Latino
- ___ Not reported: Refused or data not available
- ___ Unknown: Unsure of their ethnicity

Patient study ID number _____

Eligibility Check – Answer questions below (yes/no). All requirements must be confirmed. All dates are to be *mm/dd/yyyy*.

Registration – Inclusion Criteria

Yes No NA

Histologically or cytologically confirmed metastatic adenocarcinoma of the pancreas (ductal or undifferentiated).	_____	_____	_____
The following laboratory values obtained ≤14 days prior to registration. Earliest laboratory test date ___/___/___; latest laboratory test date ___/___/_____. NOTE: These dates pertain to the following labs only.	_____	_____	_____
• ANC ≥1500/uL. ANC = _____.	_____	_____	_____
• PLT ≥100,000/uL. PLT = _____.	_____	_____	_____
• Total Bilirubin ≤2 x institutional upper limits (patient may be stented) Total Bilirubin = _____; Total Bilirubin UNL = _____.	_____	_____	_____
• AST (SGOT) ≤ 2.5 x institutional upper limit of normal (UNL). AST (SGOT) = _____; AST (SGOT) UNL = _____.	_____	_____	_____
• Creatinine ≤2.0 x UNL. Creatinine = _____; Creatinine UNL = _____.	_____	_____	_____
• Magnesium ≥ LOWER limit of normal (LNL). Magnesium = _____. Magnesium LNL = _____.	_____	_____	_____
ECOG performance status (PS) of 0 or 1. ECOG Performance Status = _____.	_____	_____	_____
Life expectancy ≥3 months.	_____	_____	_____
≥18 years of age. Age = _____.	_____	_____	_____
Ability to understand and the willingness to sign a written informed consent document.	_____	_____	_____
Negative serum pregnancy test done ≤ 7 days prior to registration, for women of childbearing potential only. Not a woman of childbearing potential (<i>check NA</i>) vs. negative pregnancy test date ___/___/_____. _____	_____	_____	_____
Willingness to provide mandatory stool specimen for translational studies (see Sections 6.12 and 14.3).	_____	_____	_____

All responses in above section must be “Yes” unless specified as “NA.”

Registration – Exclusion Criteria

Yes No

Islet cell, acinar cell, or cystadenocarcinomas.	_____	_____	_____
Locally advanced disease.	_____	_____	_____
Prior cytotoxic chemotherapy for metastatic disease. <u>Exceptions:</u> • Prior adjuvant chemotherapy for completely resected disease or chemoradiotherapy for locally advanced disease is allowed but must have been administered >6 months prior to registration. Treatment-related adverse events must have resolved. • Gemcitabine used as either a radiosensitizer or as maintenance therapy is allowed provided >6 months have elapsed since the last day of treatment and adverse events have resolved. • The prior adjuvant chemotherapy must not have contained an EGFR inhibitor.	_____	_____	_____
Prior anti-EGFR antibody therapy (e.g., cetuximab) or treatment with small molecule EGFR inhibitors (e.g., gefitinib, erlotinib, lapatinib).	_____	_____	_____
Radiation therapy, immunotherapy or biologic therapy ≤4 months prior to registration.	_____	_____	_____
Major surgery ≤28 days.	_____	_____	_____

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Registration – Exclusion Criteria continued

Yes No

Any of the following: <ul style="list-style-type: none"> • Pregnant women • Nursing women • Men or women of childbearing potential who are unwilling to employ adequate contraception. 	____	____
Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, or psychiatric illness/social situations that would limit compliance with study requirements.	____	____
History or known presence of central nervous system (CNS) metastases.	____	____
Clinically significant cardiovascular disease (including myocardial infarction, unstable angina, symptomatic congestive heart failure, serious uncontrolled cardiac arrhythmia) ≤1 year before registration.	____	____
Pre-existent liver dysfunction from cirrhosis or viral hepatitis.	____	____
Known positive test(s) for human immunodeficiency virus (HIV) infection or acute or chronic active hepatitis B or C infection.	____	____
Enteral hyperalimentation.	____	____

All responses in above section must be “No.”

Registration Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be *mm/dd/yyyy*.

Yes No NA

Consent form signed and dated. Date of consent __/__/____.	____	____	____
Authorization for use and disclosure of protected health information signed and dated. Non-USA institution only (check NA) vs. Date of authorization __/__/____.	____	____	____
Treatment on this protocol must commence at the accruing membership under the supervision of an NCCTG member physician.	____	____	____
Treatment cannot begin prior to registration and must begin ≤7 days after registration.	____	____	____
Pretreatment tests/procedures must be completed ≤14 days prior to registration (see Section 4.0). Earliest pretreatment test date __/__/____; latest pretreatment test date __/__/____. Note: The earliest pretreatment test date must be less than or equal to the earliest laboratory test date and the latest pretreatment test date must be greater than or equal to the latest laboratory test date.	____	____	____
Exceptions to the above dates: <ul style="list-style-type: none"> • Exception test/procedures must be completed ≤ 28 days prior to registration (see Section 4.0). Earliest exception test date __/__/____; latest exception test date __/__/____. 	____	____	____
A mandatory translational research component is part of this study; the patient will be automatically registered onto this component (Sections 3.18 and 14.3).	____	____	____
All required baseline symptoms (see Section 10.3) must be documented and graded.	____	____	____
Study drug availability checked.	____	____	____
Blood draw kit availability checked.	____	____	____
Stool kit availability checked.	____	____	____

All responses in above section must be “Yes” unless specified as “NA.”

Patient study ID number _____

Registration Check continued

Yes No

An optional translational research component is part of this study. There will be an option to select if the patient is to be registered onto this component (Sections 14.0 and 17.0). <ul style="list-style-type: none"> • Patient has given permission to give blood samples for research testing planned as part of this study. 	_____
<ul style="list-style-type: none"> • Patient has given permission to give tissue sample for research testing planned as part of this study. 	_____
At the time of registration, the following will also be recorded: <ul style="list-style-type: none"> • Patient has given permission to keep blood sample(s) for use in future research to learn about, prevent, or treat cancer. 	_____
<ul style="list-style-type: none"> • Patient has given permission to keep blood sample(s) for use in future research to learn about, prevent, or treat other health problems (for example: diabetes, Alzheimer’s disease, or heart disease). 	_____
<ul style="list-style-type: none"> • Patient has given permission to keep tissue sample(s) for use in future research to learn about, prevent, or treat cancer. 	_____
<ul style="list-style-type: none"> • Patient has given permission to keep tissue sample(s) for use in future research to learn about, prevent, or treat other health problems (for example: diabetes, Alzheimer’s disease, or heart disease). 	_____
<ul style="list-style-type: none"> • Patient has given permission to keep stool sample(s) for use in future research to learn about, prevent, or treat cancer. 	_____
<ul style="list-style-type: none"> • Patient has given permission to keep stool sample(s) for use in future research to learn about, prevent, or treat other health problems (for example: diabetes, Alzheimer’s disease, or heart disease). 	_____
<ul style="list-style-type: none"> • Patient has given NCCTG permission to give blood sample(s) to outside researchers. 	_____
<ul style="list-style-type: none"> • Patient has given NCCTG permission to give tissue sample(s) to outside researchers. 	_____
<ul style="list-style-type: none"> • Patient has given NCCTG permission to give stool sample(s) to outside researchers. 	_____
<ul style="list-style-type: none"> • Patient has agreed to be enrolled on N0392, Assessment of Patient Satisfaction with Participation in Phase II/III NCCTG Clinical Trials. 	_____

All responses in above section may be “Yes” or “No”.

Stratification Factors

ECOG Performance score:

____ 0
____ 1

Prior adjuvant chemotherapy:

____ Yes
____ No

Assigned Treatment

_____ A) GEMZAR + OS1774
_____ B) GEMZAR + OS1774 + ABXEGF

Person registering Signature _____ Registration Office specialist initials _____

Physician Signature _____ Date (mm/dd/yyyy) ____/____/____