

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

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This is a randomized Phase II study comparing the combinations of gemcitabine and erlotinib versus gemcitabine, erlotinib, and panintumimab for patients who have metastatic pancreatic adenocarcinoma, who have not receive previous therapy for metastatic disease.

### Major Inclusion Criteria:

- Histologically or cytologically confirmed metastatic adenocarcinoma of the pancreas (ductal or undifferentiated). Tissue from metastasis is not required, if primary is previously biopsied - clinical staging is permitted.
- Adequate hematologic, liver and kidney function. No hypomagnesaemia.
- Life expectancy  $\geq 3$  months.
- Willingness to provide mandatory stool specimen for translational studies.
- ECOG PS of 0 or 1.

### Major Exclusion Criteria:

- Islet cell, acinar cell, or cystadenocarcinomas.
- Locally advanced disease.
- Prior chemotherapy for metastatic disease <sup>1</sup>.
- Prior anti-EGFR therapy.
- Major surgery  $\leq 28$  days or minor surgery  $\leq 14$  days prior to entry.
- No other investigational agents  $\leq 4$  weeks prior to entry.
- History of interstitial lung disease.
- Chronic use of immunosuppressive agents <sup>1</sup>.
- No CNS mets.
- Pre-existent liver dysfunction from cirrhosis, viral hepatitis, or concomitant treatment with potentially hepatotoxic drugs.
- Positive for Hep B, C, or HIV.
- Enteral hyperalimentation.

<sup>1</sup> See protocol for more specific details.

