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CURRENTLY ENROLLING for
METASTATIC PANCREATIC CANCER

mpact

Metastatic Pancreatic Adenocarcinoma Clinical Trial
albumin-bound paclitaxel (ABI-007) + gemcitabine

**A Randomized Phase III Study of Weekly ABI-007 Plus Gemcitabine Versus
Gemcitabine Alone in Patients With Metastatic Adenocarcinoma of the Pancreas**

Primary Objective

To evaluate the efficacy of the combination of ABI-007 and gemcitabine versus gemcitabine alone
in improving overall survival in patients with metastatic adenocarcinoma of the pancreas

Key Eligibility Criteria*

- Confirmed, measurable metastatic pancreatic adenocarcinoma diagnosed ≤ 6 weeks prior to randomization
- ≥ 1 metastatic tumor measurable by CT scan
- No prior therapy for treatment of metastatic disease
- Karnofsky performance status ≥ 70
- No brain metastases
- No prior malignancy in last 5 years

N=842
Randomization (1:1)

Albumin-bound paclitaxel + Gemcitabine Arm[†]

- Albumin-bound paclitaxel 125 mg/m² IV weekly x 3
- Gemcitabine 1000 mg/m² IV weekly x 3
- 28-day cycles

Gemcitabine Arm[†]

- Cycle 1 (56-day cycle): Gemcitabine 1000 mg/m² IV weekly x 7
- Cycles 2+ (28-day cycles): Gemcitabine 1000 mg/m² IV weekly x 3

* Additional criteria apply.

[†] Patients continue treatment until disease progression or unacceptable toxicity, palliative radiotherapy to a target lesion is required, consent is withdrawn, or physician's choice. End-of-study assessments will be performed for all patients who are removed from study.

Investigational use of albumin-bound paclitaxel.