ABI-007-PANC-007

*Nab*-Paclitaxel Plus Gemcitabine in Subjects With Locally Advanced Pancreatic Cancer (LAPC): an International, Open-Label, MultiCenter, Phase II Study (LAPACT)
ABI-007-PANC-007 (LAPACT): Phase II Trial of nab-Paclitaxel + Gemcitabine for LAPC

Treatment Effect on Pancreatic and Metastatic Lesions in the MPACT Trial

- Percent change in the sum of target lesions from baseline for nab-P + Gem vs Gem alone
  - Pancreatic: median -22.15% vs -7.02% (P < 0.001)
  - Nonpancreatic: median -24.27% vs -8.74% (P < 0.001)

- The approximate 3-fold greater shrinkage for nab-P + Gem vs Gem in pancreatic and nonpancreatic lesions is similar to the difference in ORR (23% vs 7%, P < 0.001)
**ABI-007-PANC-007 (LAPACT): Phase II Trial of nab-Paclitaxel + Gemcitabine for LAPC**

**PC Classification**

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<th>Classification</th>
<th>Disease Stage</th>
<th>Features</th>
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| **Resectable** (≈ 10%) | 0, IA, IB, IIA, IIB | - No distant metastases  
- No evidence of SMV or portal vein abutment, distortion, tumor thrombus, or venous encasement  
- Clear fat planes around the celiac axis, hepatic artery, and SMA |
| **Borderline resectable** (≈ 10%) | III | - No distant metastases  
- SMA encasement < 180°; SMV/portal impingement  
- Short-segment SMV occlusion  
- Celiac encasement < 180° (tail)  
- Abutment/encasement of hepatic artery |
| LAPC (≈ 30%) | III | - No distant metastases  
- SMA encasement > 180°  
- SMV/portal vein occlusion  
- Any celiac abutment (head) or celiac encasement > 180° (body/tail)  
- Aortic invasion or encasement; lymph node metastases beyond field of resection |
| MPC (≈ 60%) | IV | - Presence of extrapancreatic disease |

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*a Percentages do not total 100%, likely because “borderline resectable” was included in the “locally advanced/unresectable” category.

LAPC, locally advanced pancreatic cancer; MPC, metastatic pancreatic cancer; SMA, superior mesenteric artery; SMV, superior mesenteric vein.

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**LAPACT: Study Design**

- Previously untreated, locally advanced, unresectable pancreatic cancer
  - Planned N = 110

- nab-P
  - 125 mg/m² qw 3/4
  - + Gem
  - 1000 mg/m² qw 3/4
  - × 6 cycles

- For patients without disease progression or unacceptable toxicity after 6 cycles, Investigator’s choice:
  - nab-P + Gem, chemoradiation, or surgical resection

- Periodic follow-up for PFS, OS

- CT or MRI scans will occur every 8 weeks
• Primary endpoint:
  —TTF—the time after the first dose of study therapy to therapy discontinuation due to disease progression, death, or the start of a non–protocol-defined anticancer therapy
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LAPACT: Select Inclusion Criteria

• Histologically or cytologically confirmed pancreatic adenocarcinoma
  – Unresectable according to radiographic criteria or exploration:
    • SMV and portal vein: occlusion, thrombosis, or encasement extending several centimeters
    • SMA: tumor abutment > 180 degrees or thrombosis of artery
    • Celiac axis: abutment or encasement of the celiac axis
    • Lymph nodes: involvement

• ECOG PS of 0 or 1
• Acceptable hematology parameters and blood chemistry levels
  – ANC ≥ 1500 cells/mm³
  – Platelet count ≥ 100,000/mm³
  – Hemoglobin ≥ 9 g/dL
  – AST and ALT ≤ 2.5 × ULN
  – Total bilirubin ≤ 1.5 × ULN
• Statistical design
  – A sample size of 100 patients will have 80% power at a one-sided alpha of 0.05 to detect a 30% increase in median TTF from 5.1 months (median TTF in the phase III MPACT study) to 6.6 months
  – Assumes a 10% dropout rate
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Global Enrolment

Total Active Sites: 41
Total Enrolment: 67
Target Enrolment: 110

- Canada: 5 Pts randomized, 5 Sites
- France: 17 Pts randomized, 6 Sites
- Italy: 5 Pts randomized, 2 Sites
- Spain: 9 Pts randomized, 5 Sites
- USA: 31 Pts randomized, 23 Sites