INFLUENCE OF PRIMARY PANCREATIC TUMOR LOCATION ON EFFICACY AND TREATMENT EXPOSURE IN THE MPACT TRIAL OF NAB-PACLITAXEL (NAB-P) PLUS GEMCITABINE (GEM) VS GEM ALONE FOR PATIENTS WITH METASTATIC PANCREATIC CANCER (MPC)


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Aim: The prognosis of pancreatic cancer may be influenced by the primary tumor location within the pancreas. In the phase III MPACT trial, nab-P + Gem demonstrated superior efficacy vs Gem alone as first-line treatment for MPC (median overall survival [OS]: 8.5 vs 6.7 mo; hazard ratio [HR] 0.72; P < 0.001; median progression-free survival [PFS], 5.5 vs 3.7 mo; HR 0.69; P < 0.001). The effect of primary pancreatic tumor location on efficacy and treatment exposure in the MPACT trial is reported.

Methods: Previously untreated pts (N = 861) with MPC and baseline bilirubin ≤ upper limit of normal were randomized 1:1 to receive nab-P 125 mg/m² + Gem 1000 mg/m² on d 1, 8, and 15 of each 28-d cycle or Gem 1000 mg/m² weekly for 7 wk followed by 1 wk of rest (cycle 1) and then d 1, 8, and 15 of each 28-d cycle (cycle ≥ 2). In this analysis, OS, PFS, and treatment exposure were analyzed according to primary tumor location.

Results: nab-P + Gem demonstrated superior survival vs Gem alone, independent of the primary tumor location (Table). Tumor location did not appear to be associated with any differences in treatment exposure. The median cumulative dose of nab-P was 1500 mg/m² vs 1375 mg/m² in pts who had primary tumors in the head vs tail or body. The most common grade ≥ 3 adverse events in pts with pancreatic head tumors for nab-P + Gem vs Gem (neutropenia [35% vs 26%], peripheral neuropathy [21% vs 1%], and fatigue [18% vs 9%]) were similar to those in the intent-to-treat (ITT) population.

Table: 692P Efficacy by Primary Tumor Location

<table>
<thead>
<tr>
<th>Efficacya</th>
<th>nab-P + Gem</th>
<th>Gem</th>
<th>HR</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head n (%)</td>
<td>191 (44)</td>
<td>180 (42)</td>
<td>-</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Median OS, mo</td>
<td>9.3</td>
<td>6.5</td>
<td>0.59</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Median PFS, mo</td>
<td>5.5</td>
<td>3.7</td>
<td>0.53</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Other n (%)</td>
<td>237 (55)</td>
<td>246 (57)</td>
<td>-</td>
<td>0.033</td>
</tr>
<tr>
<td>Median OS, mo</td>
<td>8.1</td>
<td>6.9</td>
<td>0.80</td>
<td>0.013</td>
</tr>
<tr>
<td>Median PFS, mo</td>
<td>5.4</td>
<td>3.7</td>
<td>0.74</td>
<td></td>
</tr>
</tbody>
</table>

* PFS by independent assessment.

Conclusions: nab-P + Gem demonstrated superior efficacy vs Gem alone. This effect remained clinically and statistically significant regardless of the primary tumor location. These findings are consistent with previous efficacy findings in the ITT population from MPACT. No new safety signals were observed.

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